From:	Yvette Tan
To:	medboardconsultation
Subject:	Consultation on contemporary and unconventional medicine and emerging treatments'
Date:	Friday, 5 April 2019 12:42:36 PM
Attachments:	My Practice.docx celldangerresponse_healingcycle (1).pdf

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Dear medical board,
Attached is my submission for the above consultation.

regards,
-
Dr Yvette Tan
[redacted]

My Practice

My patient profile

Patients see me for the following reasons :

1. complex medical issues, often, been through specialists and exhaustive investigations and still not feeling better; or told that nothing more can be done for them.
2. Chronic medical conditions not responsive to allopathic medicine or suffering side effects of therapy impacting quality of life.
3. Mental health issues either on antidepressants/ antipsychotics/ anxiolytics and still not functioning well; or not keen to be on psychiatric medications and want a more natural approach to feeling better; or on psychiatric medications and wanting to wean themselves off of them safely.
4. Children with behavioural issues, learning difficulties and parents wanting a more holistic approach to helping their children. Some of them are already on Ritalin on the like, whilst some are trying to avoid going down that path.
5. Preparation for pregnancy or subfertility.
6. Building health resilience for those already in good health
7. Improving health and exercise performance.
8. Optimizing health and vitality for those feeling their age, or knowing that they feel older than their age.
9. Parents of infants who want to work towards a more gentle vaccination schedule.

Most patients come to see me based on recommendations from other patients because they are looking for a doctor who 'does not simply push pharmaceuticals', and will help them work on optimizing health through natural, holistic approaches

My clinical approach:

All patients will sign a consent form that informs them of my approach: including my approach, the lack of published evidence of some of the recommendations and the possible conflict of interests in some of my recommendations, before I will see them as a patient.

I spend about one and half hours on the first visit with them.

In the first 50minutes I go through the intake form which they should have completed prior to their appointment and take an exhaustive history of their symptoms, medical diagnosis, previous treatments, family history, function, time line of illnesses etc.
I spend 5 minutes on targeted physical examination based on the clinical story.

I spend the next 25 minutes presenting to them the frame work of how I will work through their issues whilst educating them on what I have identified as their possible root causes of diseases. I spend a fair bit of time going through lifestyle habits that have contributed significantly to their illness, in particularly, diet, exercise, breathing, sleeping, stress reduction and how to optimize them. I would especially highlight how important mental wellbeing is critical for good health and help them make the connection of how stress can adversely affect the autonomic nervous system and lead to long term physical health problems; and how emotional healing work is critical part of recovery from chronic illnesses. I would emphasize that these lifestyle changes are foundational to good health, and that even without further testing and taking of medications or supplements, the body would already be able to respond positively to this.

I then spend the last 10 minutes talking about further testing and treatments that might be of benefit if the patients want to delve deeper, or should they still not get the results that they are after.

I always emphasize that the tests recommended are entirely optional, but useful should we need further understanding of their symptoms.

I will highlight whenever I deviate from allopathic medicine in terms of hypothesis, testing and treatments. I also always give the patients the allopathic approach to their clinical situation as well as the naturalistic approach, and allow them to choose the path they would like to take. I assure them that I am happy to support them with whichever path they choose to take. I assure them that I am not afraid to use pharmaceuticals if needed, but prefer to work upstream with them to correct underlying root causes of their problem if possible or if they so wish. I have found that addressing root causes and optimizing physiology and body's biochemistry through targeted nutrients and supplementation and lifestyle changes based on the emerging science of nutrigenomics , metabolomics and sociogenomics, provide deeper , longer lasting results, and is capable of changing the trajectory of health in my patients.

Most of my patients appreciate this approach. Their first comment is often," finally I find a doctor who is willing to listen to my story and try to work with me to understand how I got so sick". They are also relieved to find a doctor who is open and well versed with both allopathic and naturalistic approaches. They share that they often keep what they doing from their previous treating doctors for fear of judgement or outright disapproval; and value the opportunity to share candidly with myself what they are doing or considering doing. Many of them are confused by what they are learning on their own, often from Dr Google, or Dr Neighbour; and have unfounded fears or bias against allopathic medicine. They allow me to provide them accurate information so that they can form a more balanced view of both allopathic and naturalistic medicine and how both can be used to serve their needs with good effect. It has allowed them to make more informed decisions of their healthcare including sticky matters like vaccinations. They also recognize that they can change their path at any time. At each review, both allopathic and naturalistic options are offered to them.

I usually see my patients 2-4 weekly for the first four subsequent visits, each about an hour long. This gives me enough opportunity to teach the patients new skills and help them establish a more optimal lifestyle. After this, most patients see me 3 to 6 monthly for a catch up, and then more infrequently once they are confidently on their health path.

My doctor patient relationship:

The relationship I have with my patients is one of deep respect and regard. Whilst I am the medical expert, they are the expert of their bodies and therefore their experience and ideas, concerns and expectations are taken seriously when developing the treatment plan. I take great pains to provide health education, so that patients can be confident and empowered to make great health choices for themselves.

I have been blown away by the ability of my patients to advocate for themselves and their children, and how much they would like to be proactive about their health. Rather than feel threatened by this, I welcome their engagement and input as we work together to find solutions for their health problem

I see myself as a health coach and guide more and more especially with chronic diseases, as I help patients navigate through their life journey, so that their health goals are not compromised.

My toolkit

There are various strategies in my tool kit that are not conventional, including testing as well treatments. I have come to include them in my toolkit because of the limitations of allopathic medicine.

Whilst these tests and treatments have not had acceptance from the allopathic medical community, it has been used by other health professionals around the world with good results. These emerging modalities,(which are supported by basic science, environmental science, soil science, quantum science, mitochondrial science, toxicology research etc) would probably take some time to become mainstream, but I am willing to be an early adopter if it has the potential to benefit my patients. My approach has always been: 'first, to do no harm'. I have a high regard for evidence based medicine, but I also recognize its limitations. I have come to realize that despite the best research methodologies; research is still limited in its ability to attribute cause and effect accurately; since like most things in life, every outcome is influenced by a multitude of factors both seen and unseen. Good doctors who have been successful in reversing Alzheimer's or autism have had difficulty getting their work published because their interventions, which is multifaceted intervention protocol , doesn't fit the gold standard randomized double control trial demanded by evidence based medicine. I have come to appreciate, too, that experience often precedes the science; and therefore there is great value in learning from doctors who have already gotten the experience of positive results. I would demand for solid evidence when the risk of the intervention is high and the benefit suspect. The chosen modalities in my toolkit are safe, with the main risk to the patients, a waste of their money and time, but have the potential of significant benefit. In my mind, the most relevant evidence at the end of the day, is that the individual patient feels better. It does not really matter if the other 100 patients benefitted or not from the treatment, but how the individual has responded. For patients who have been through the mill trying out lots of treatment, they will be able to discern this for themselves quite quickly.

Outcome of care

I have successfully helped a lot of my patients to wean off medications for pain, mental health and chronic diseases. I have been able to keep my patients out of hospital, and helped them preempt a downward spiral of accumulating more chronic diseases to their name. Despite seeing a high load of mental health patients, my prescription of psychiatric medications is lower than the average doctor, and I rarely initiate pain killers, as I offer patients other options to deal with pain that would facilitate the body healing from injury more expediently. I have got a 93year old patient still winning golf tournaments, (I have weaned him off all his pharmaceutical medications, and he takes a handful of supplements to support his body) and a 97 year old patient who sees me for emotional healing work to optimize her wellbeing. I feel that I have contributed to reducing health care cost to both the patients and the system. I also feel that the life skills that I teach my patients not only benefit them but their family and the world around them. Many of my patients report to me what they are teaching their friends and family to also help them improve their health.

My message to the medical board.

I have taken pains to describe to you what I do in my practice. The intention is to assure you that your concerns of my exploitation of patients and putting them in any danger is unfounded.

As you make your decisions regarding further regulation of myself and other doctors practicing the way I do, I hope you will not dumb us down, only so that we conform with our allopathic colleagues who focus on symptomatic care and protocol driven medicine often disregarding context or flow on detrimental effects of treatment downstream. It would be a great disservice to our patients and society at large and it would give the message to the public and the medical profession that this approach is not to be encouraged, and in fact to be deterred. If this is the intention, then I cannot in good conscience and professionally reduce my practice as demanded by your regulation. Sadly I may have to admit that I am in the wrong profession, and may have to find another way of serving my patients. If the way I practice is appreciated by the medical board as positive, and a good model of care, then regulations can be made to encourage medicine practiced this way, so that more patients can benefit from this approach.

With the rise in health care cost from chronic disease burden, a paradigm shift from symptomatic, one size fits all medicine, to a holisitc personalized model of care with emphasis on fundamentals like the right nutrition, sleep, breathing, exercise and stress reduction is needed. Please ensure that regulation supports the shift clearly and not confuse the medical fraternity further with mixed messages. I attach a paper from mitochondrion which I feel is seminal, that support the need for this paradigm shift.

The patient profile is rapidly changing, and now with open access to health information, a lot of our patients are at the cutting edge of this. We run the risk of losing our relevance to their health needs if we continue with our reductionistic and paternalistic approach. Patient empowerment through informed consent and collaboration will be the way forward to cost effective health and safe health care. Safe both for patients and the treating doctor.

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Metabolic features and regulation of the healing cycle—A new model for chronic disease pathogenesis and treatment

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ABSTRACT

Without healing, multicellular life on Earth would not exist. Without healing, one injury predisposes to another, leading to disability, chronic disease, accelerated aging, and death. Over 60% of adults and 30% of children and teens in the United States now live with a chronic illness. Advances in mass spectrometry and metabolomics have given scientists a new lens for studying health and disease. This study defines the healing cycle in metabolic terms and reframes the pathophysiology of chronic illness as the result of metabolic signaling abnormalities that block healing and cause the normal stages of the cell danger response (CDR) to persist abnormally. Once an injury occurs, active progress through the stages of healing is driven by sequential changes in cellular bioenergetics and the disposition of oxygen and carbon skeletons used for fuel, signaling, defense, repair, and recovery. > 100 chronic illnesses can be organized into three persistent stages of the CDR. One hundred and two targetable chemosensory G-protein coupled and ionotropic receptors are presented that regulate the CDR and healing. Metabokines are signaling molecules derived from metabolism that regulate these receptors. Reframing the pathogenesis of chronic illness in this way, as a systems problem that *maintains* disease, rather than focusing on remote trigger(s) that *caused* the initial injury, permits new research to focus on novel signaling therapies to *unblock* the healing cycle, and restore health when other approaches have failed.

1. Introduction

Much of modern Western medicine is based on the principles of acute interventions for poisoning, physical injury, or infection. These principles trace to historical figures like Paracelsus (1493 1541), Ambroise Paré (1510 1590), and Louis Pasteur (1822 1895). These acute care interventions are now widely used in the modern fields of pharmacology, toxicology, urgent care, emergency medicine, and surgery. When caring for acute disruptions in health, the careful identification of the trigger, or cause of the problem, and the anatomical location of the defect, is an important part of good medical care. However, when dealing with chronic illness, treatments based on the rules of acute care medicine have proven less helpful, and can even cause harm by producing unwanted side effects (Qato et al., 2018).

In chronic illness, the original triggering event is often remote, and may no longer be present. Emerging evidence shows that most chronic illness is caused by the biological *reaction* to an injury, and not the initial injury, or the agent of injury itself. For example, melanoma can be caused by sun exposure that occurred decades earlier, and post traumatic stress disorder (PTSD) can occur months or years after a bullet wound has healed. If healing is incomplete between injuries, more severe disease is produced. If a new head injury is sustained before complete healing of an earlier concussion, the clinical severity of the second injury is amplified, and recovery is prolonged. This occurs even when the energy of the second impact was less than the first. Progressive dysfunction with recurrent injury after incomplete healing occurs in all organ systems, not just the brain. Chronic disease then results when cells are caught in a repeating loop of incomplete recovery and re injury, unable to fully heal. This biology is at the root of virtually every chronic illness known, including susceptibility to sequential or recurrent infections, autoimmune diseases like rheumatoid arthritis, diabetic heart and kidney disease, asthma and chronic obstructive pulmonary disease (COPD), autism spectrum disorder (ASD), chronic fatigue syndrome (CFS), cancer, affective disorders, psychiatric illnesses, Alzheimer dementia, and many more.

Great strides have been made since the 1940s in the treatment of

Abbreviations: TOGLEs, transporters Opsins G protein-coupled receptors ligands and effectors; CDR, cell danger response; ASD, autism spectrum disorder; CFS, chronic fatigue syndrome; DAMPs, damage-associated molecular patterns; DARMs, damage-associated reactive metabolites; PTSD, post-traumatic stress disorder; M0, uncommitted; M1, pro-inflammatory; M2, anti-inflammatory mitochondrial polarization

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acute illness. This success has decreased infant mortality, lowered mortality from infections and trauma, and has improved survival after heart attacks, strokes, and cancer. However, this success has led to a sea change in medicine. Instead of spending the majority of time treating acute illness, physicians and health care workers in 2018 now spend the majority of time and effort caring for patients with chronic disease. Over $2.5 trillion is spent every year in the US to care for patients with chronic illness (Burke, 2015). While it has been tempting to treat this rising tide of chronic disease by using the principles that have proven so successful in acute care medicine, a growing literature supports the conclusion that every chronic disease is actually a whole body dis ease a *systems problem* that cannot be solved using the old paradigm. For example, autism, bipolar disorder, schizophrenia, Parkinson, and Alzheimer disease each affect the brain, but are also characterized by whole body metabolic abnormalities that are measureable in the blood and urine (Gevi et al., 2016; Han et al., 2017; He et al., 2012; Varma et al., 2018; Yoshimi et al., 2016). Rheumatoid arthritis affects the joints, but also has metabolic abnormalities in the blood that show an activated cell danger response (CDR) (Naviaux, 2014) for several years before the onset of clinical joint disease (Surowiec et al., 2016). Cor onary artery disease affects the heart, but is the result of long standing abnormalities in metabolism called “the metabolic syndrome” (Mottillo et al., 2010).

All chronic diseases produce systems abnormalities that either block communication (signaling), or send alarm signals between cells and tissues. Cells that cannot communicate normally with neighboring or distant cells are stranded from the whole, cannot reintegrate back into normal tissue and organ function, and are functionally lost to the tissue, even when they are surrounded by a normal mosaic of differentiated cells. As this process continues, two different outcomes are produced, depending on age. If the block in cell cell communication occurs in a child, then the normal trajectory of development can be changed, leading to alterations in brain structure and function, and changes in long term metabolic adaptations of other organs like liver, kidney, microbiome, and immune system. If the communication block occurs in adults, then organ performance is degraded over time, more and more cells with disabled or dysfunctional signaling accumulate, and age re lated deterioration of organ function, senescence, or cancer occurs.

Blocked communication and miscommunication inhibit progress through the healing cycle, and prevent normal energy , information , and resource coordination with other organ systems (Wallace, 2010). This predisposes to additional damage and disease. When chronic dis ease is seen as a systems problem in which the healing system is blocked by key metabolites that function as signaling molecules metaboki nes new therapeutic approaches become apparent that were hidden before. What follows is a description of our best current model of the metabolic features of the healing cycle. Future research will be needed to flesh out additional details.

2. Materials and methods

2.1. Bioinformatic analysis of P2Y1R related proteins

A TBLASTN search of the human genome was conducted using the P2Y1R protein (Uniprot P47900, ENSP00000304767) as the reference. The top 156 matching sequences were recovered. After removal of pseudogenes, partial, and duplicate sequences, the top 91 unique genes recovered ranged from 257 to 388 amino acids in length, shared a 22% 42% identity with P2Y1R, had blast scores of 70 740, and e va lues of 8×10^{-10} to 2×10^{-66}. TAS2R46, a bitter taste receptor, en coded by the *T2R46* gene, was used as an outgroup for tree construc tion. Sequence alignments were performed using the clustal w method in MegAlign (Lasergene v15.1, DNAStar Inc., Madison, WI). Tree ana lysis and visualizations were performed using FigTree v1.4.3 (http://tree.bio.ed.ac.uk/software/figtree/).

2.2. Bioinformatic analysis of P2X1R related proteins

A TBLASTN search of the human genome was conducted using the P2X1R protein (Uniprot P51575, ENSP00000225538) as the reference. The only related genes found were the other 6 known P2X receptors. A BLASTP search of related proteins recovered 46 splice variants of the 7 known ionotropic P2X receptors. The 7 top sequences were 352 399 amino acids in length, sharing 38% 52% identity with P2XR1, and had blast scores of 291 831, and e scores of 3×10^{-91} to 5×10^{-149}.

2.3. Gene ontology

A gene ontology analysis of the 91 P2Y1R related genes was per formed using the online gene list analysis tools available on the Panther Gene Ontology website (http://www.pantherdb.org/). The top 6 path ways had gene enrichments > 3 times the expected threshold, ex plained 98% of the connections, and had false discovery rates from 0.02 to 2.7×10^{-65}.

3. Need for a systems biology of healing

The classical signs of inflammation that begin the process of wound healing have been known since before the time of Hippocrates (c. 460 370 BCE). Medical students today still learn the classical Latin terms for the signs of inflammation as *rubor*, *tumor*, *calor*, *dolor*, and *functio laesa* (redness, swelling, heat, pain, and loss of function). In United States, the curriculum at most medical schools does not yet in clude a specific course on the molecular systems biology of healing. The descriptive elements of injury and healing are taught in traditional courses like pathology, histology, and during clinical service on the surgical and burn wards. However, a dedicated systems biology course, describing our current understanding of the choreographed changes in cell metabolism, biochemistry, gene expression, cell structure, cell function, and pathophysiology that occur after injury and during healing, is missing. The rapidly growing fields of Integrative (Rakel, 2018), Functional (Baker et al., 2010), and Natural (Pizzorno and Murray, 2013) Medicine devote considerable attention to the broader, multi dimensional study of whole body healing as it applies to the treatment of chronic illness. However, a modern synthesis of functional and traditional medicine with state of the art medical technology di rected at the molecular aspects of healing has not yet been achieved.

4. Metabolomics A new lens for chronic disease medicine

The newest “omics” technologies to be added to the systems biology toolbox are metabolomics (Jang et al., 2018) and lipidomics (Harkewicz and Dennis, 2011). Rapid advances in these emergent technologies were made possible by technological advancements in mass spectrometry that have occurred since about 2012. In 2018, we are still at least 10 years behind the technical sophistication of geno mics, but a flood of new publications using metabolomics has revealed the first outlines of a missing link that connects the genes and disease. Whole body *chemistry* appears to be this link (Fiehn, 2002).

5. Metabolites as both matter and information

Chemistry provides the link between genotype and phenotype in two ways: (1) cell metabolism is the direct result of gene environment interactions (G × E = metabolism), and (2) chemicals (metabolites) made by and processed by the cell have a dual biology as both *matter* and *information*. Metabolites have a well known function as *matter*; metabolites are the physical building blocks used for cell growth, structure, function, repair, and as energy and electron carriers. In ecosystem theory, this metabolic matter represents resources for system structure, function and growth, and for energy to support ecosystem connectivity and resilience to purturbation (Bernhardt and Leslie,

2013). Many metabolites also have a lesser known function as *in formation*; they bind specific receptors to change behavior, regulate fetal and child development, shape the microbiome, activate neu roendocrine and immune systems, and regulate the autonomic and enteric nervous systems.

Metabolites like ATP, S adenosylmethionine (SAMe), acetyl CoA, NAD+, and others are used to modify DNA and histones directly to alter gene expression through epigenetics (Naviaux, 2008; Nieborak and Schneider, 2018; Wallace and Fan, 2010). Other metabolites like α ketoglutarate, succinate, fumarate, iron, FAD, and oxygen act as es sential cofactors for epigenetic modifications. These metabolites, and others like propionyl CoA, butyryl CoA, succinyl CoA, myristoyl CoA, farnesyl diphosphate, and UDP glucose, also alter the function of other proteins by post translational modifications of nuclear transcription factors and enzymes throughout the cell as a function of real time changes in metabolism. Finally, dozens of metabolites act as signaling molecules called metabokines, by binding to dedicated cell surface re ceptors.

6. The healing cycle

The healing process is a dynamic circle that starts with injury and ends with recovery. This process becomes less efficient as we age (Gosain and Dipietro, 2004), and reciprocally, incomplete healing re sults in cell senescence and accelerated aging (Valentijn et al., 2018). Reductions in mitochondrial oxidative phosphorylation and altered mitochondrial structure are fundamental features of aging (Kim et al., 2018). The changes in aging are similar to programmed changes that occur transiently during the stages of the cell danger response needed for healing (Naviaux, 2014) (Fig. 1). Although the circular nature of healing seems obvious from daily experience with cuts, scrapes, and the common cold, the extension of this notion to a unified theory to explain the pathophysiology of chronic complex disease has only recently be come possible. Technological advancements in mass spectrometry and metabolomics have permitted the characterization of 4 discrete stages in the healing cycle (Fig. 1). The first of these is the health cycle, which requires wakeful activity alternating with periods of restorative sleep. The health cycle will be discussed after first reviewing the 3 stages of the cell danger response: CDR1, CDR2, and CDR3. Aspects of the CDR include the integrated stress response (ISR) (Lu et al., 2004) and the mitochondrial ISR (Khan et al., 2017; Nikkanen et al., 2016; Silva et al., 2009). While all aspects of the CDR are coordinated by nuclear mi tochondrial cross talk, the precise controls of the transitions between the stages of the CDR are largely unknown.

The following is a current model based on evidence drawn from many experimental studies. As such, the details must be considered provisional. The 3 stages of the CDR are energetically and metabolically distinct. The smooth transition from one step to the next is choreo graphed by metabolic signaling and regulated by 3 sequential quality control checkpoints, CP1, CP2, and CP3 (Fig. 1). The checkpoints ap pear to interrogate mitochondrial and cellular function. The completion of each stage of the CDR appears to be decided largely on a cell by cell basis. These checkpoints are not regulated by a single, deterministic signaling molecule. Checkpoints are better considered as gates con trolled by the synergistic effects of multiple permissive and inhibitory signals. The concentration of a particular signaling molecule is de termined in part by the total number of cells in a tissue in each stage of the CDR. Both local and systemic signals are used. As such, the checkpoints that regulate progress through the healing cycle are probability gates. Based on real time chemical signals and

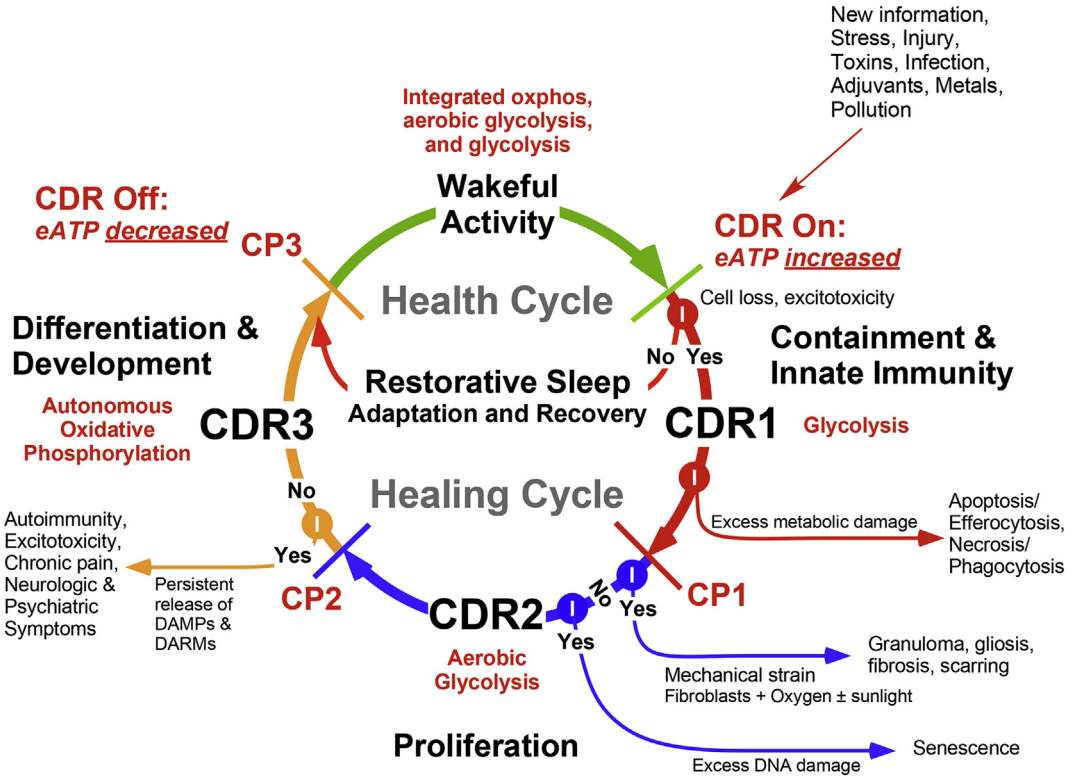

Fig. 1. A metabolic model of the health and healing cycles. Health is a dynamic process that requires regular cycling of wakeful activity and restorative sleep. The healing or damage cycle is activated when the cellular stress exceeds the capacity of restorative sleep to repair damage and restore normal cell-cell communication. CDR1 is devoted to damage control, innate immunity, inflammation, and clean up. CDR2 supports cell proliferation for biomass replacement, and blastema formation in tissues with augmented regeneration capacity. CDR3 begins when cell proliferation and migration have stopped, and recently mitotic cells can begin to differ entiate and take on organ-specific functions. **Abbreviations**: eATP; extracelllular ATP; CP1–3: checkpoints 1–3; DAMPs: damage-associated molecular patterns; DARMs: damage-associated reactive metabolites.

Table 1
Provisional classification of stage-specific healing cycle disorders.*

CDR1 Disorders	CDR2 Disorders	CDR3 Disorders
Innate Immune Disorders	**Proliferative Disorders**	**Differentiation Disorders**
–HPA Axis, ATP, Lipids, mtDNA	–mTOR, p21, HIF, PHDs	–DARMs, Mito Polarization
Systemic Inflammatory Response Syndromes (SIRS)	Dyslipidemia	Autism spectrum disorder
Multiple Organ Dysfunction Syndrome (MODS),	Hyperuricemia	Chronic Fatigue Syndrome
Septic shock	Diabetes	Post-traumatic stress disorder
Acute Respiratory Distress Syndrome (ARDS)	Diabetic retinopathy	Fibromyalgia, Chronic pain syndromes, Allodynia
Allergies, asthma, atopy	Hypertension	Neuropathic pain syndromes
Chronic infections (fungal, bacteria, viral, parasitic)	Heart disease	Complex regional pain syndromes
Gulf War Illness (GWI)	Peripheral vascular disease	Obsessive Compulsive Disorder
Tinea pedis, Tinea versicolor, Tinea corporis, Tinea barbae	Cerebral vascular disease	Generalized Anxiety Disorder
Histoplasmosis, Coccidiomycosis	Inflammatory bowel disease	Major depressive disorder
Aspergillosis, Chronic mucocutaneous Candidiasis,	(Crohn's, Ulcerative colitis)	Bipolar disorder
Sporotrichosis, Cryptococcosis,	Non-alcoholic steatohepatitis	Migraine headaches
Sarcoidosis, Chronic granulomatous disease,	(NASH), Cirrhosis	New daily persistent headaches
Chlamydia, Listeriosis,	Idiopathic pulmonary fibrosis	POTS, PANS, PANDAS
Toxoplasmosis, Bartonellosis,	Benign prostatic hyperplasia	Schizophrenia, acute psychosis
Syphilis, Helicobacter, Neisseria,	Keloid formation	Parkinson, Alzheimer
Vibrio cholerae, Tuberculosis,	Subacute spinal cord injury	Multiple sclerosis, Tourette's
Non-tuberculous mycobacteria infections, Leprosy, Lyme,	Dermal vasculitis,	Dystonia syndromes, Lupus Selected epilepsies, Behcet's
Typhoid, Malaria, Leishmaniasis,	Temporal arteritis,	Scleroderma, Sjögren's,
Onchocerciasis, Schistosomiasis	Kawasaki coronary arteritis	Polymyalgia rheumatica
Trypanosomiasis, Filariasis	Cancers and Leukemias	Ankylosing spondylitis
		Amyotrophic lateral sclerosis
Ecosystem disorders		Chronic traumatic encephalopathy
Coral reef fungal infections (*Aspergillus*),		Traumatic brain injury
Coral bleaching disorder (*Vibrio*),		Selected post-stroke syndromes
Shrimp black gill disease (*Hyalophysa*),		Wakeful delta wave activity (EEG)
Microsporidial gill disease in fish,		Hashimoto's thyroiditis
Colony collapse disorder in honey bees,		Psoriasis, eczema
White nose disease in bats (*Geomycosis*),		Alopecia areata, vitiligo
Chytridiomycosis in frogs and salamanders,		Autoantibodies to intrinsic factor
Potato plague (*Phytophthera*),		Rheumatoid arthritis
Sudden Oak Death (*Phytophthera*),		Osteoarthritis
Tea leaf blister,		Macular degeneration
Coffee rust,		Presbyopia, presbycusis
Cacao tree witch's broom fungus,		Diabetic neuropathy
White pine blister rust (*Cronartium)*,		Diabetic nephropathy
Sudden Aspen Decline (*Cytospora*)		Irritable bowel syndrome
		Adaptive Energy Conservation and Survival States
		Dauer, diapause, torpor, estivation
		Hibernation, Persister cells
		Plant seed embryo formation
		Caloric restriction metabolism
		Longevity metabolism

* Subdivisions occur within each of the 3 main stages of the CDR.

mitochondrial function, each cell has a certain probability of entering the next stage of healing. This probability is 0% 100% based on cell specific metabolism and the net effect of all the metabokines in the millieu around the cell. For any given cell, one step in the healing cycle cannot be entered until the previous step has been completed and mi tochondrial function in that cell is ready for the next step. Restoration of normal communication between neighboring and distant cells is the last step of the healing cycle and is monitored by checkpoint 3 (Fig. 1). Some of the chronic illnesses and ecosystem disruptions that result from stage specific interruptions in the healing cycle are listed in Table 1. Further studies will be needed to refine this provisional classification.

7. CDR1 Glycolysis, M1 mitochondria

The function of CDR1 is the activation of innate immunity, intruder and toxin detection and removal, damage control, and containment (Fig. 1). The level of inflammation produced in CDR1 is adjusted ac cording to need. A major trigger of CDR1 appears to be a fundamental change in cellular organization or order, generalized as thermodynamic entropy (Cunliffe, 1997). Physical disruption of gap junctions that connect and coordinate cell function in tissues can activate the CDR. Other triggers include bacteria, viruses, fungi, protozoa, or exposure to biological or chemical toxins. In all cases, extracellular ATP and other metabokines are released from the cell to signal danger. This happens through stress gated pannexin/P2X7 channels in the membrane and through an increase in vesicular export of ATP through SLC17A9, the vesicular nucleotide transporter (VNUT), and related transporters (Sakaki et al., 2013).

Mitochondria change their function rapidly under stress. Within minutes, the normal anti inflammatory M2 form of mitochondria that is specialized to meet the metabolic needs of the differentiated cell, is polarized toward pro inflammatory, M1 mitochondria (Naviaux, 2017) (Fig. 2). This initiates the oxidative shielding response needed for da mage control and containment (Naviaux, 2012). When less oxygen is consumed by mitochondria for energy production by oxphos, more oxygen becomes available for synthesis of oxylipin signaling molecules (Gabbs et al., 2015) and reactive oxygen species (ROS) for defense. The incorporation of oxidized nucleotides produced during the oxidative shielding response that occurs during CDR1 into newly synthesized mitochondrial DNA, and the release of small fragments of this new oxy

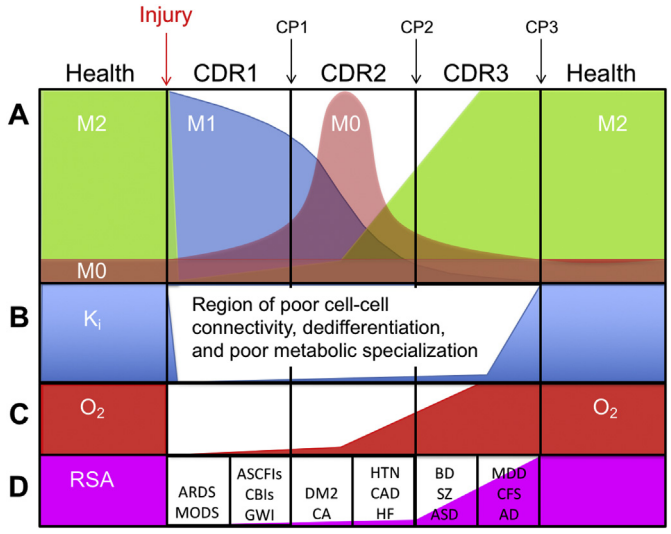

Fig. 2. Systems coordination during the healing cycle. **A.** Functional polarization of mitochondria. **B.** Connectivity (K_i): tissue and cellular responsiveness to circadian, autonomic, and neuroendocrine coordination. **C.** Tissue oxygen consumption and delivery (O_2). **D.** Ventral Vagal Complex (myelinated parasympathetic) Tone (RSA; respiratory sinus arrhythmia). Examples of chronic illnesses within subdivisions of the CDR are provisional. **Abbreviations**: M2—anti-inflammatory mitochondria specialized for oxidative phosphorylation. M1—pro-inflammatory mitochondria specialized for cellular defense in cells that use glycolysis for ATP synthesis. M0—uncommitted mitochondria adapted for rapid cellular growth and aerobic glycolysis. CP1–3: checkpoints 1–3. K_i—inter-organ, intercellular, intracellular, inter-organellar connectivity and communication. RSA: respiratory sinus arrhythmia. ARDS—acute respiratory distress syndrome. MODS—multiorgan dysfunction of sepsis. ASCFIs—Acute Staphylococcal and chronic fungal infections. CBIs—chronic bacterial infections (TB, Helicobacter, Lyme, etc). GWI—Gulf War Illness. DM2—Type 2 Diabetes. CA—cancer. HTN—hypertension. CAD—coronary artery disease. HF—heart failure. BD—Bipolar Disorder. SZ—schizophrenia. ASD—autism spectrum disorder. MDD—Major Depressive Disorder. CFS—chronic fatigue syndrome. AD—Alzheimer dementia.

mtDNA into the cytosol is required for NLRP3 inflammasome activation (Zhong et al., 2018). Release of newly synthesized double stranded mitochondrial RNA into the cytosol also helps defend the cell during CDR1 by activating type I interferons and the antiviral response (Dhir et al., 2018).

A useful metaphor for communicating this transformation to lay audiences is as a change from powerplants to battleships. The power plant function of M2 mitochondria is adapted for oxidative phosphor ylation. The battleship function of M1 mitochondria is adapted for ROS (peroxides, superoxide, and singlet oxygen), reactive nitrogen species (RNS: nitric oxide and peroxynitrite), and reactive aliphatic hydro carbons (RAHs: epoxides, acyl , and amine aldehyde) production. With M1 polarization, energy coupled mitochondrial oxygen consumption drops, and cellular energy production switches to glycolysis and lactate production. This switch in bioenergetics is protective to cells when capillaries have been disrupted and the availability of oxygen for aerobic metabolism is compromised. Ischemic preconditioning exposes cells to a transient, sublethal stress that increases ROS and induces HIF1α and TIGAR (TP53 induced glycolysis and apoptosis regulator) for 1 3 days (Semenza, 2011; Zhou et al., 2016). This treatment causes cells to enter CDR1, decreasing mitochondrial oxidative phosphoryla tion and increasing glycolysis. The result is a dramatic reduction in cell death when preconditioned cells in CDR1 are exposed to potentially lethal insults within the 1 3 day window of protection. If no cells are lost, preconditioned cells return directly to CDR3 and the health cycle via the direct stress response track that is used regularly during re storative sleep (Fig. 1).

A cell that adopts the CDR1 phenotype must functionally disconnect many lines of communication with neighboring cells. This is needed to make the metabolic and physical changes needed for cellular defense under threat. Communication with neighboring cells during this time is dramatically decreased and changed. The decrease in, and restructuring of cell cell communication represents a kind of cellular autism that is not just beneficial, but required to initiate the healing process. However, because organs require tight cell cell communication and coordination for optimum function, this disconnection of cells from the whole comes at a cost; normal organ function is temporarily decreased while cells pass through the steps of healing (Fig. 1). This contributes to the "*functio laesa*", loss of function, described as a canonical feature of early wound repair and inflammation. Removal of debris and damaged cells is accomplished by the combined actions of polymorphonuclear and mononuclear phagocytes recruited to the site, venous, and lym phatic drainage. This loss of function can last for weeks or months after an injury before recovery occurs. One well studied example is the stunned myocardium that can occur after acute myocardial infarction. After injury, a segment of heart muscle can remain alive and perfused, but non contractile for months. When recovery occurs, it is accom panied by a shift in metabolism from glycolysis (CDR1), through a blended transition phase of aerobic glycolysis (CDR2), back to oxidative phosphorylation (CDR3) (Figs. 1 and 2). This sequence is associated with an increase in mitochondrial fusion proteins and normal fatty acid oxidation (Holley et al., 2015; van der Vusse, 2011; Vogt et al., 2003), and a restoration of normal cell cell communication needed for elec tromechanical coupling. CDR1 ends with passage through checkpoint 1 (CP1, Figs. 1 and 2). CP1 requires the creation of a less oxidizing and less inflammatory extracellular environment that is conducive for shifting the thermodynamic balance from monomer to polymer synth esis needed for rebuilding RNA, DNA, proteins and membranes, and for the recruitment of previously quiescent satellite and stem cells into cell division in CDR2.

8. CDR2 Aerobic glycolysis, M0 mitochondria

The function of CDR2 is biomass replacement (Fig. 1). Every organ and tissue has an optimum number and distribution of differentiated cell types that are needed for healthy organ function. When cells are lost, they must be replaced or organ function cannot be fully restored. Once the damage associated with the initial injury, infection, or toxin exposure has been cleared or contained in CDR1, the cells that were lost need to be replaced. In CDR2, stem cells are recruited to replace the lost biomass. Stem cells are present in all tissues throughout life. When activated, they will enter the cell cycle. The mitochondria in stem cells and their immediate daughter cells exist in a youthful, metabolically uncommitted state called "M0" (Fig. 2A). M0 mitochondria help to facilitate aerobic glycolysis, also known as Warburg metabolism, which is needed for rapidly growing cells. During aerobic glycolysis, ATP is synthesized by glycolysis. However, M0 mitochondria still consume oxygen and electrons. Instead of using the potential energy gradient for synthesizing ATP by oxidative phosphorylation, M0 mitochondria dis sipate the energy gradient by releasing metabolic intermediates needed for polymer synthesis and cell growth. For example, mitochondria are needed for de novo pyrimidine synthesis. The mitochondrial inner membrane protein, dihydroorotate dehydrogenase (DHODH) is re quired for the 4th step in de novo pyrimidine synthesis to make orotic acid. Orotic acid is needed to make UMP, which is then used to make all the Us, Cs, and Ts the cell needs for RNA and DNA synthesis, and for activated intermediates like UDP glucose for receptor glycoprotein synthesis and glycogen synthesis, and CDP choline for phosphati dylcholine synthesis. M0 mitochondria also supply succinyl CoA and glycine for delta amino levulinic acid (δ ALA, also known as 5 ALA), porphyrin, and heme synthesis needed for cytochromes and he moglobin. M0 mitochondria also synthesize and release citric acid, which can be used either in the cytosol or nucleus by ATP citrate lyase

Table 2
Functional characteristics of the CDR and health cycle.

Feature	CDR1	CDR2	CDR3	Health Cycle
Cell Metabolism	Glycolysis	Aerobic glycolysis	Oxidative phosphorylation	Balanced oxphos, glycolysis, and aerobic glycolysis
Cellular Autonomy[1]	High	High	Decreasing	Low
Ventral Vagal[2] **Autonomic Tone**	Low	Low	Increasing	High, with diet and activity-related cyclic variations under circadian and seasonal control
Function	Containment, pathogen removal, toxin sequestration, Innate Immunity, clean-up	Proliferation, Biomass Restoration, Blastema Formation*	Differentiation, Cell-cell communication, Metabolic Memory, Adaptive Immunity, Detoxification	Cell-cell communication, Metabolic complementarity, Development, Learning, Fitness, Restorative sleep, Healthy Aging, Cancer suppression, neuroendocrine systems integration
Diseases	Chronic Infections, allergies, MODS, SIRS, ARDS	Diabetes, Heart disease, Cancer, Fibrosis	Pain, Autonomic, Affective, Psychiatric, Neurologic, Immune/Autoimmune, and Microbiome dysfunction, other target organ dysfunction	n/a
CDR Gene Examples	NRF2, CRF2, IDO1, NOXs, NFkB, HO1, PARs, REXO2, eIF2α, STAT1/2, MMP9, IRF1, IRF3/4, SP1, IFNα/β, IL1β, UMP-CMPK2, TNFα	mTOR, HIF1α, AhR, p53, p21, $p16^{INK4A}$, c-myc, PHDs, BRCA1/2, ATR, other DNA repair enzymes, Nanog*, Sox2*, Oct4*, Isl1*	AMPK, FOXO, PPARs, BCL2, P1, P2Y, P2X, CD38, RXRs, CD38, CD39, CD73, IL6, FXR, IFNγ, IL17, IL4, TGF, Iron-sulfur cluster proteins, Mfn1/2, Opa1, Intestinal disaccharidases	n/a

Abbreviations: MODS—multiple organ system dysfunction in sepsis; SIRS—systemic inflammatory response syndrome; ARDS—acute respiratory distress syndrome; NOXs—NADPH oxidases; PARs—protease activated receptors (F2R/PAR1, F2RL1/PAR2, F2RL2/PAR3); IRF1—interferon regulatory factor 1; PHDs—HIF1α-targeting prolyl hydroxylase domain proteins; PPARs—peroxisome proliferator activated receptors; RSA—respiratory sinus arrhythmia; HRV—heart rate variability. [1]Cell autonomy is associated with cellular disconnection, whole body stress, and activation of the HPA axis. [2]Ventral vagal tone via myelinated fibers from the *nucleus ambiguus*, measured by RSA and/or HRV. *For embryonic development and multilineage regeneration in some animals.

(ACYL) as a mobile source of acetyl CoA. In the cytosol, the acetyl CoA can be used to make fatty acids, triacylglycerol for energy reserves, and phospholipids for new cell membranes. In the nucleus, the acetyl CoA is used by histone acetyl transferases (HATs) to place epigenetic marks on chromatin to regulate new gene expression and DNA repair (Sivanand et al., 2017). CDR2 is a stage in which cells with too much DNA damage exit the cell cycle and can adopt an irreversible senescence phenotype, with secretion of exosomes, inflammatory cytokines, growth factors, and proteases (He and Sharpless, 2017).

CDR2 is also the stage in which fibroblasts and myofibroblasts are recruited to help close wounds or "wall off" an area of damage or infection with scar tissue that could not be completely cleared in CDR1 (Fig. 1). CDR2 is also when blastema formation occurs in certain aquatic organisms like the Mexican salamander (eg, *Axolotl)*, flatworms (eg, *Planaria),* and *Hydra* that display the capacity for multi lineage tissue regeneration after injury (Heber Katz and Messersmith, 2018). Less extensive blastema formation is seen as a feature of healing and multi lineage regeneration in the MRL mouse, a strain of laboratory mouse with remarkable healing abilities (Heber Katz, 2017; Naviaux et al., 2009).

Recent studies have begun to target metabolic enzymes that regulate CDR2. A class of proline hydroxylase domain proteins (PHDs) that mark HIF1α for proteasome degradation acts as a tissue oxygen sensor. Drug inhibition of a PHD increased HIF1α stability and expression in the presence of normal oxygen, permitted blastema formation, and improved epimorphic regeneration in strains of mice that cannot otherwise fully regenerate after injury (Zhang et al., 2015). During CDR2, dividing and migrating cells are unable to establish long term metabolic cooperation between cells because their location within tissues is continuously changing. Only after cells have stopped growing and migrating can they begin to establish long term symbiotic relationships with neighboring cells that build physiologic reserve capacity, provide resistance to re exposure to a similar environmental danger, and benefit the whole. Once cells exit the cell cycle and establish durable cell cell contacts through gap junctions and other structural connections, they can exit CDR2 and enter CDR3 (Figs. 1 and 2).

9. CDR3 Cell autonomous oxphos, M2 mitochondria

The functions of CDR3 include cellular differentiation, tissue remodeling, adaptive immunity, detoxification, metabolic memory, sensory and pain modulation, and sleep architecture tuning (Fig. 1). Cells that enter CDR3 stop dividing and establish cell cell connections with their neighbors. Newly born cells, that were generated during cell growth from satellite or stem cells in CDR2, must undergo a process of cellular education that involves adjustments in gene expression, cell structure and metabolism, to best adapt to existing tissue conditions before they can take on the role of a fully differentiated cell in the mature organ and tissue. Healing remains incomplete in CDR3 until newly born cells differentiate by receiving metabolic instructions and materials from older, neighboring cells that carry the metabolic memories and programming from before the time of the tissue injury that activated the CDR.

Mitochondria in CDR3 cells repolarize from M0 to M2 organelles (Fig. 2). Most remaining M1 mitochondria also repolarize to the M2, anti inflammatory phenotype needed for differentiated cell function and oxidative phosphorylation (oxphos). This is accomplished in part by re establishing permanent access to oxygen and nutritional resources, while permitting free release of metabolites and waste products to neighboring capillaries and lymphatics. Oxygen, iron, and sulfur delivery are differentiating and promote mitochondrial biogenesis of iron sulfur clusters. Iron sulfur clusters are needed for differentiated cell functions like oxidative phosphorylation, the anti viral response, protein translation, genome integrity maintenance, and organ specific physiologic functions (Braymer and Lill, 2017). Outer mitochondrial membrane fusion proteins like mitofusin 1 and 2, and the inner membrane fusion protein Opa1 are also needed to achieve normal mitochondrial network morphology and fully differentiated tissue function (Cao et al., 2017; Del Dotto et al., 2017) (Table 2).

As differentiation proceeds, cells also reestablish connections with the autonomic nervous system and tissue lymphatics. All blood vessels and most tissues receive innervation from the sympathetic and parasympathetic nervous systems. Metabolite and waste product removal helps to provide remote information to and from organs like the brain, liver, intestines, and kidney. Each of these organs participates in regulating whole body absorption, secretion, metabolism, function, and behavior according to chemical signals that are circulated in the blood. Tissue specific detoxification restarts in CDR3 and continues through the health cycle. A major regulator of checkpoint 3 is purinergic signaling. The health cycle cannot be reentered until extracellular levels of ATP and related ligands decrease. A decrease in eATP at the completion of CDR3 is a permissive signal that facilitates new and old cells to re establish the physical, autonomic, and neuroendocrine contact needed for health (Fig. 1, Table 2). In many instances, the completion of CDR3 results in improved baseline physiogic performance and extended reserve capacity compared to before the stress or injury. At a cellular level, this is called hormesis (Fig. 3) and lies at the heart of adaptive improvements in both baseline performance and reserve capacities in response to many forms of stress. These stresses can range from exercise to radiation or chemical toxin exposure, drug tachyphylaxis, to stimuli that result in long term memory (Calabrese and Baldwin, 2003; Chen et al., 2013; Ristow, 2014).

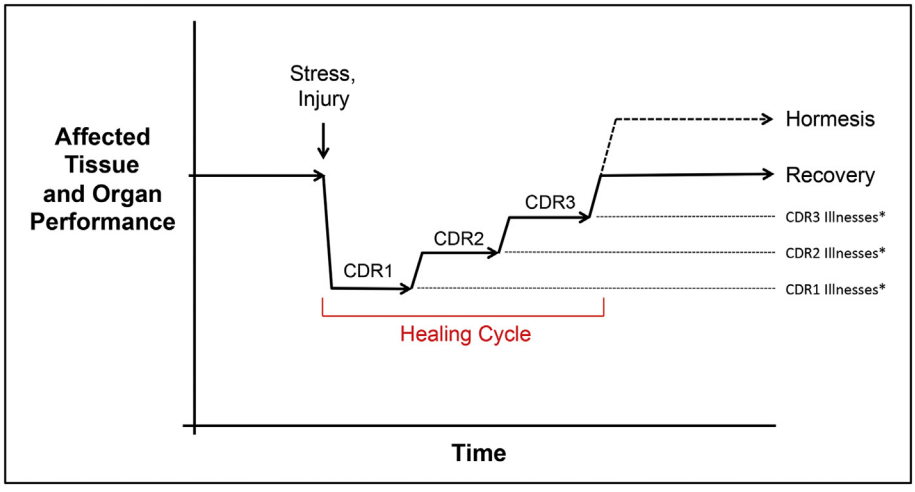

Fig. 3. Timeline of the healing cycle and hormesis. Despite a cascade of events triggered by injury, and hundreds of molecular abnormalities that can be measured in each stage of the healing cycle, the arrow of time is not reversed to heal damage and normalize abnormal functions. The metabolic stages of the healing cycle proceed sequentially forward in time. Healing follows a similar path regardless of the mechanism of injury. *Once a chronic illness occurs, there is little practical difference between the severities possible for CDR1, 2, or 3 disorders. With rare exceptions, each can produce a spectrum from mild disability to death.

10. The health cycle Harmonized and periodized bioenergetics

The function of the health cycle is to promote wakeful activity, restorative sleep, normal child development, adaptive fitness, and healthy aging. The health cycle is characterized by the balanced, integrated, and periodized usage of all three bioenergetics programs; glycolysis, aerobic glycolysis, and oxidative phosphorylation (Fig. 1). Health requires brain integration and coordination of organ function and whole body metabolism using neuroendocrine and autonomic controls. Wakeful activity and a varied, seasonally appropriate diet that is sourced from local ecosystems and consumed during daytime hours helped select the gene pools that humans received from their ancestors, up until about the last 200 years. Disruptions in this pattern of seasonal food availability, the increasing prevalence of night shift work, and the decline of traditionally active outdoor lifestyles, have led to new selection pressures on our inherited gene pool. Modern mass spectrometry and metabolomics have helped us achieve a more detailed understanding of the importance of dietary cycling that occurs naturally with the seasons and periodically with occasional short fasts that promote health throughout the year (Mattson et al., 2018).

Cruciferous vegetables in a healthy diet contain isothiocyanates like sulforaphane that act rapidly as chemical pro oxidants to transiently decrease the amount of intracellular glutathione. This short term pro oxidant effect produces a long term increase in antioxidant defenses by blocking KEAP1 and Cullin 3 dependent ubiquitination, and permitting the translocation of NRF2 (nuclear factor 2 erythroid related factor 2) to the nucleus. In the nucleus, NRF2 acts as a transcription factor to up regulate over a dozen different cytoprotective proteins like glutamate cysteine ligase (GCL) to increase glutathione synthesis, glutathione S transferase (GST) for xenobiotic detoxification, and heme oxygenase 1 (HO1) for local synthesis of carbon monoxide (CO) at sites of heme extravasation to attenuate M1 polarized mitochondrial pro inflammatory effects. While oxygen inhibits the stability of HIF1α, the same conditions increase the stability and support the transcriptional activity of NRF2. Acute stress leads to a normal, NRF2 activation response. In contrast, chronic activation by stress ultimately desensitizes and decreases NRF2 activation, and permits long term increases in inflammation associated NFkB activation (Djordjevic et al., 2015). The normal health cycle requires the daily modulation of these cycles of increased and decreased oxygen related redox stress associated with wakeful activity and restorative sleep (Figs. 1 and 2).

11. Exercise and healthy aging

Exercise is medicine. Wakeful activity is essential for the health cycle (Fig. 1) and healthy aging. Regular exercise appears to be the single most important habit known that mitigates the degenerative effects of aging. Moderate exercise creates a natural stimulus that facilitates restorative sleep and repair by creating balanced activation of all the stages of the healing cycle. In many important metabolic ways, exercise “reminds” the body how to heal and promotes disease free health throughout life. Exercise is adaptogenic (Panossian, 2017). Exercise increases physiologic reserve capacity and resilience to periodic exposure to stress or acute illness. Organ reserve capacity diminishes with age (Atamna et al., 2018). Exercise combats this loss. Even just 15 min of moderate to vigorous exercise per day each week lowers all cause mortality by 22%. Older adults who completed > 30 min/day for 5 days each week had a 35% decrease in mortality over 7 10 years (Hupin et al., 2015; Saint Maurice et al., 2018).

12. Slow wave sleep and healing

Sleep is medicine. Slow wave sleep (SWS) and the associated increase in parasympathetic autonomic tone are important for healing and recovery during rapid growth in childhood (Takatani et al., 2018). Disruptions in SWS and parasympathetic tone during sleep are risk factors for many chronic illnesses (Carney et al., 2016; Rissling et al., 2016). Delta waves in an electroencephalogram (EEG) are defined as high amplitude (100 300 μV) slow waves (0.5 2 Hz). Delta waves are a normal feature of the deep stages 3 and 4 of sleep. Rapid growth and recovery after high intensity exercise are associated with an increase SWS in children (Dworak et al., 2008; McLaughlin Crabtree and Williams, 2009). In classical mitochondrial diseases like Alpers syndrome, the need for brain repair is so great that delta waves are seen in the EEG even while awake (Naviaux et al., 1999). Wakeful delta wave activity (slow wave activity) has also proven to be a useful biomarker in studies of traumatic brain injury (Huang et al., 2016). Reciprocally, new methods are being developed to promote wakeful delta waves as therapy in patients with traumatic brain injury (Huang et al., 2017).

13. Metabokines and their receptors

13.1. Metabokines, neurotransmitters, and immune regulators

While it is clear that both exercise and sleep influence metabolism, how does the cell leverage changes in metabolism to influence progression through the healing cycle? Metabolites have long been known to act as signaling molecules in neuroscience. All the classical neurotransmitters are technically metabokines. Molecules like serotonin, melatonin, acetylcholine, glutamate, aspartate, glycine, D serine, GABA, dopamine, norepinephrine, epinephrine, histamine, anandamide, and adenosine are all products of metabolism that act as signaling molecules by binding to cellular receptors. There are even circulating classes of memory T cells that contain the enzyme choline acetyl transferase (ChAT) and release acetylcholine in response to vagal nerve stimulation to activate important anti inflammatory macrophages expressing the nicotinic acetylcholine 7 alpha subunit (nAch7α) (Baez Pagan et al., 2015; Rosas Ballina et al., 2011). This signaling function of metabolites has not been widely incorporated into discussions of metabolic control of cellular functions and development. Metabolites act directly as informational molecules by acting as ligands for specific G protein coupled and ionotropic receptors. Secreted metabokines alter the informational content of the extracellular millieu in many ways. One of these is through a process called *exosignalling* (Pincas et al., 2014), which can prime cells for contextually dependent, non linear quantitative and qualitative responses to hormones and other signaling molecules. Purinergic receptors respond to adenine and uracil nucleotides and nucleosides (Verkhratsky and Burnstock, 2014). Nineteen (19) purinergic receptors are present in the human genome (Fig. 4). Four P1 receptors are 7 transmembrane G protein coupled receptors (GPCRs) that respond to adenosine (ADORA1, 2A, 2B, and 3). Eight GPCRs are single exon, P2Y receptors (1, 2, 4, 6, 11, 12, 13, and 14) that respond to ATP, ADP, UTP, UDP, and UDP glucose (Fig. 4A). Seven are multi exon, ionotropic P2X receptors (1 7) that respond to extracellular ATP and act as ion channels for calcium and potassium (Fig. 4B).

13.2. Dendrogram and gene ontology analysis

To investigate the number of receptor systems that are related to the release of ATP and other nucleotides from stressed and damaged cells, a TBLASTN search was performed of human proteins related to the P2Y1 receptor, a prototypic purinergic receptor. The P2Y1R is a conventional, single exon, metabotropic, G protein coupled receptor with 7 transmembrane domains. A dendrogram of the top 91 P2YR1 related proteins revealed a possibility of 6 groupings according to amino acid sequence and function in the healing cycle (Fig. 5A). These are: A) hemostasis, pH monitoring, cannabinoid, Krebs cycle, leukotriene, and purinergic signaling, B) lysophospholipid, sphingolipid, cannabinoid, and metabolite signaling, C) eicosanoid, lactate, niacin, short chain fatty acid (acetate, propionate, butyrate, and the ketone body β hydroxybutyrate), and protease signaling, D) viral co receptors, glucose/sucrose signaling, pro inflammatory and anti inflammatory peptides E)

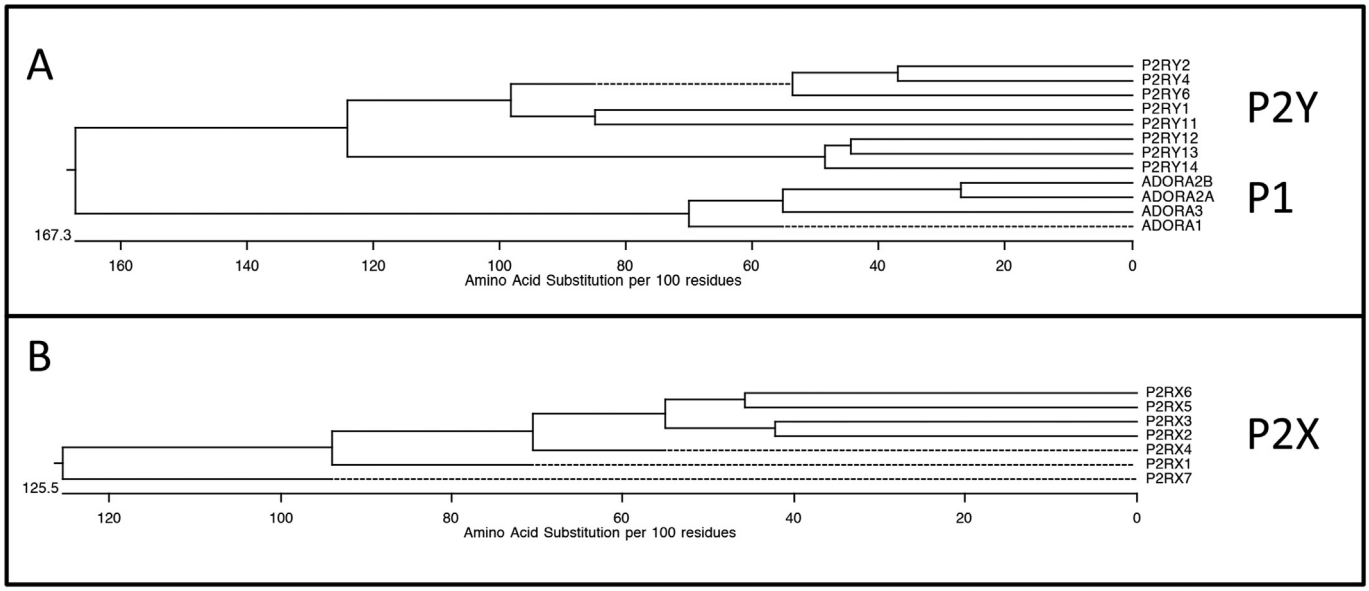

Fig. 4. Purinergic receptors. **A.** Metabotropic G-Protein Coupled Purinergic Receptors, P2Y receptors respond to ATP, ADP, UTP, UDP, UDP-glucose, and/or Ap4A (diadenosine tetraphosphate). P1 receptors respond to adenosine receptor A (ADORA1, 2A, 2B, and 3). **B.** Ionotropic Purinergic Receptors. P2X receptors respond to ATP and/or Ap4A.

neuropeptides and other peptide hormones, and F) chemokines. A gene ontology analysis of the pathways that were enriched in this set of 91 proteins showed that about 50% of the pathways were involved in calcium signaling, 20% with cell movement, and the remainder divided among molecular regulation, immune response, apoptosis, and sensory processing (Fig. 5B).

13.3. Ligand analysis

The ligands that bind to the 91 P2YR1 related proteins differ in size. Eight of the 91 related receptors in Fig. 5A use nucleotides, eg, ATP, ADP, UTP, UDP etc., as their canonical ligand. Another 35 of the receptors use other common metabolites and neurotransmitters like lactic acid, succinate, alpha ketoglutarate, glutamate, short chain fatty acids, long chain fatty acids, eicosanoids, cannabinoids, sphingolipids, lysophospholipids, serotonin, and melatonin. A total of 43 of 91 (47%) receptors respond to metabokines less than about 400 Da in size. Twenty four (26%) use peptides 4 to about 80 amino acids long (400 8000 Da), often released by proteolytic activation from an inactive precursor. Twenty one (22%) respond to chemokines that are 8000 to 10,000 Da in size. Among these are receptors that are essential for innate immunity and for healing and regeneration after injury. For example, the CXCR4 binds to the chemokine CXCL12, also known as stromal derived factor 1 (SDF1), which negatively regulates multilineage regeneration (Heber Katz, 2017). Four (4%) of the 91 GPCRs related to P2YR1 are constitutively active, or have ligands that are not yet known (Table S1).

14. The TOGLEs that regulate metabolism

Transporters, opsins, G protein coupled receptors, and their ligands and effectors (TOGLEs) are a diverse group of proteins that share a common evolutionary origin (Saier Jr. et al., 2016; Yee et al., 2013). The single, most diverse superfamily of genes found in metagenomic surveys of ocean picoplankton (bacteria) are the bacterial rhodopsins (Venter et al., 2004). Interestingly, the opsins are related to a group of phosphate, sulfur, cystine, heavy metal, organic acid, salt, and sugar transporters that share similar structures and transmembrane topologies. Difficulties in sensing, handling, or responding to many of these molecules have been documented in complex diseases like autism spectrum disorder (ASD) (Adams et al., 2011). These transporters and opsins are related to G protein coupled receptors (GPCRs) that constitute over 800 genes in the human genome (Gether, 2000). The functional tie that binds all the TOGLEs together is their role in monitoring the cellular environment for signs of nutrient resources, recognizing friends, signaling danger, and facilitating social and reproductive behaviors. The very receptors that now permit cells to monitor minute changes in the chemical environment are descended from ancestral genes for color vision, smell, and taste (Liman, 2012).

15. Hormone target resistance and axis suppression by the CDR

End organ resistance to hormone signaling is an intrinsic part of the CDR. Once a tissue suffers injury, a shift to dependence on local chemical cues and paracrine signaling is essential. Remote decision making by endocrine glands cannot provide “boots on the ground”, real time instructions to injured cells when bidirectional lines of communication are disrupted. A shift from fully integrated and periodized metabolism to cell autonomous metabolism is an obligate feature of CDR stages 1 and 2 (Figs. 1 and 2, Table 2). *Re* establishment of hormone sensitivity begins during CDR3, and is required for re entry into the health cycle (Fig. 1, Table 2). All known mechanisms of hormone resistance have been cataloged. Hormone release, target cell hormone metabolism (Incollingo Rodriguez et al., 2015), and intracellular hormone signaling can each be attenuated by the CDR. End organ resistance during the CDR can affect all the major endocrine systems. Thyroid, adrenal cortical glucocorticoid and mineralocorticoid, and renin angiotensin system attenuation states are common in patients with chronic fatigue syndrome (CFS). The most common forms of stimulus response dysregulation lead to complex endocrine syndromes that do not fit classical medical definitions of deficiency or failure because residual hormone production can usually be shown by physiologic stimulation, but is suppressed. These complex disorders have sometimes been called thyroid or adrenal exhaustion syndromes. On the other side of the intracellular energy spectrum, insulin resistance associated with caloric excess and inactivity can lead to type 2 diabetes mellitus (DM2). In all these end organ resistance states, the treatments that have been most effective are metabolic, diet, and lifestyle interventions that restore normal bidirectional function of the endocrine system. In contrast, chronic treatment with the hormone in question typically leads to

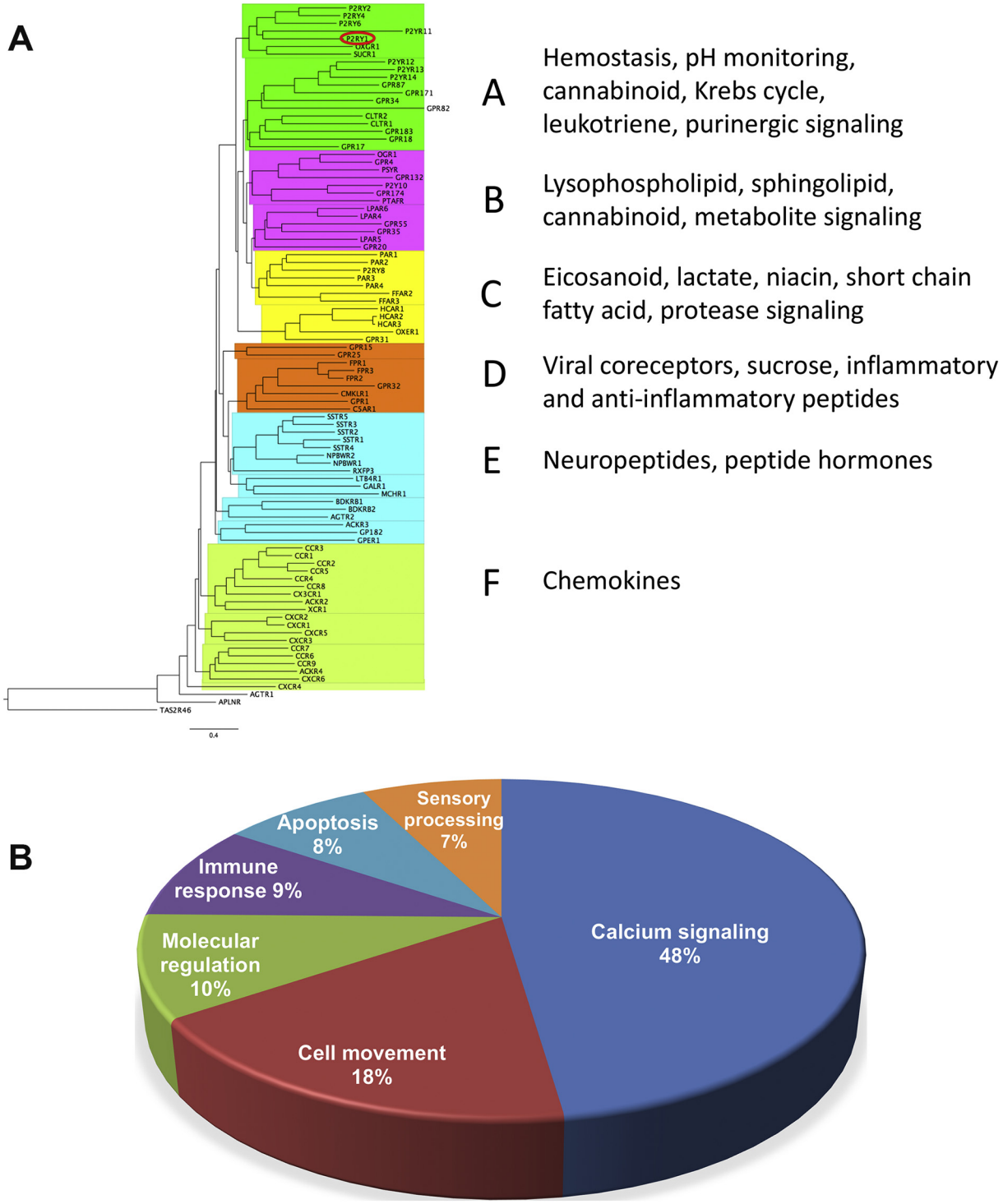

Fig. 5. P2Y1R-related GPCR genes in the human genome. **A.** Dendrogram analysis. P2RY1 is circled to indicate the reference protein used in the TBLASTN search that recovered the 91 proteins analyzed. Colored functional groupings were loosely associated with sequence similarity. **B.** Gene ontology pathway enrichment analysis. (N = 91 P2Y1R-related genes; PANTHER analysis).

iatrogenic side effects, and dependence on the exogenous hormone. Knowledge of the cell autonomy requirement of the CDR helps reframe the causal mechanisms behind these previously unconnected syn dromes (Figs. 1 3, and Table 2).

16. Vagal target resistance and axis suppression by the CDR

The activity of the parasympathetic nervous system measured along a gradient of environmental safety is U shaped. The ventral vagus complex (VVC) is comprised of myelinated fibers from the *nucleus ambiguus* to the vagus nerve. The VVC is most active under conditions of social attachment, caloric security, and physical safety. At the other extreme is the dorsal vagal complex (DVC). The DVC is also called the dorsal motor nucleus of the 10th cranial nerve (DMNX). The DMNX sends unmyelinated fibers to the vagus nerve. The DMNX is most active acutely under life threatening conditions, and periodically in synchrony with the VVC during predictable changes in physiology associated with feeding, sleep, and reproduction. Since the majority of wakeful activity

occurs between these two extremes of absolute safety and absolute danger, a large part of life is spent at the bottom of the "U", poised between the neurophysiologic and neuroendocrine commitment to one or the other. A shift to the left on the U curve is in the direction of health and fitness (Lucas et al., 2018). A shift to the right leads to chronic illness, disability, and death. When the CDR is chronically activated, the coordination between the two limbs of the vagus is disrupted. This results in disinhibiting the sympathetic nervous system and the hypothalamic pituitary adrenal (HPA), which dominate during illness (Fig. 2, Table 2).

Disruption of cellular communication, and the associated increase in cell autonomous and paracrine signaling by metabokines during the CDR is tightly associated with either a disruption in normal parasympathetic tone from the VVC, or end organ resistance to cholinergic signals. This is typically quantified by measurements of respiratory sinus arrhythmia (RSA) and heart rate variability (HRV) (Porges, 2007). Substages of the CDR occur during the transition between a fully active ventral vagus complex in health, its rapid inhibition by CDR1, and its gradual return in CDR3. The return of oxygen utilization by healing tissues during CDR2 and CDR3 is associated with increases in RSA and HRV (Fig. 2, Panel D). Increased RSA and HRV are also known to be associated with endurance exercise and aerobic health (De Meersman, 1992, 1993).

When the normal cyclic variations in vagal outflow are disrupted during the CDR, a number of autonomic abnormalities occur. These include postural orthostatic tachycardia syndrome (POTS), and autoimmune disorders like pediatric autoimmune neuropsychiatric syndrome (PANS), and pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS). All three of these disorders have autoimmune components that appear tied to a decrease or absence of normal anti inflammatory signaling by the vagus. Vagal efferents mobilize T cells from gut associated lymphoid tissue (GALT) in the GI tract. The T cells then induce the anti inflammatory M2 macrophage phenotype through nicotinic acetylcholine 7 alpha (nAch7α) receptors (Baez Pagan et al., 2015). Vagal efferents also inhibit cysteinyl leukotriene release by mast cells via nicotinic cholinergic signaling (Mishra et al., 2010). Cysteinyl leukotrienes C4, D4, and E4 are also called the slow reacting substances of anaphylaxis, and bind to receptors closely related to P2Y receptors (CTLR1 and 2 in Fig. 5A). Additional support for the important role played by cholinergic signaling from the vagus comes from the use of nicotinic cholinergic antagonists for neuromuscular blockade (NMBA) during anesthesia. Drugs like suxamethonium and atracurium are used for NMBA, and block nicotinic cholinergic signaling everywhere receptors exist, not just at the neuromuscular junction. These drugs are associated with a risk for anesthesia induced allergic and non allergic immediate type hypersensitivity reactions, especially in patients with known allergies and mast cell hypersensitivity (Laroche et al., 2017). Even POTS has recently been shown to be associated with autoantibodies to the angiotensin II receptor (Yu et al., 2018).

17. Tissue mosaics and cellular dyssynchrony in healing

Healing is necessarily heterogeneous and dyssynchronous at the cellular level. This occurs for three reasons: 1) all differentiated tissues and organs are mosaics of metabolically specialized cells with differing gene expression profiles that permit the metabolic complementarity needed for optimum organ performance, 2) physical injury, poisoning, infection, or stress do not affect all cells equally within a tissue, and 3) once a tissue is injured, cells that have not yet completed the healing cycle have not yet reintegrated back into the tissue mosaic, creating chinks or weaknesses in tissue defenses from the old injuries that makes a tissue more vulnerable to new injuries. This process gradually decreases organ function and cellular functional reserve capacity as we age.

Severe threats or injuries cause cells to disconnect from neighboring cells. The initial stages of healing require cell autonomous actions. If a an entire organ or tissue is threatened, millions of cells will activate the cell danger response (CDR) program in an effort to survive, at the expense of their normal differentiated cell functions. If injury, or the threat of injury, is severe enough, signals are sent from the brain to alter organismal behavior to limit the chances of worsening injury, or the chance of spreading contagion to family or community members. The brain coordinates this stereotyped sickness behavior during activation of the CDR (Dantzer and Kelley, 2007; Naviaux, 2014). The rate at which cells are able to progress through the healing cycle differs according to the local severity of the danger and the ability of the host to mount protective defenses. Metabolic memory of past exposures primes the cellular response to future exposures, even when the original trigger or stress is no longer present.

18. Genes, drugs, and devices that regulate stages of the CDR

To date, the only drug that has been tried explicitly as a treatment for a blocked CDR to promote healing is suramin (Naviaux et al., 2014; Naviaux et al., 2015; Naviaux et al., 2017; Naviaux et al., 2013). A recent study of a device for pulse based transcranial electrical stimulation to stimulate restorative, wake time delta wave activity and to improve the quality of sleep has shown promise in the treatment of traumatic brain injury (TBI) (Huang et al., 2017). Brain delta waves are associated with a shift in metabolism that facilitates brain and body repair, recovery, and healing. Once the healing cycle (Figs. 1 and 2) is understood in greater detail, many other drugs and treatments may emerge that are designed to provide novel approaches to treating CDR associated chronic diseases (Table 1). While increased ATP release from cells is a part of each of the 3 stages of the CDR (Fig. 1), other metabolites and genes play more selective roles. By studying the metabolites, genes, and cell types involved in each stage, more selective therapies can be developed. For example, the NRF2 and hypothalamic pituitary adrenal (HPA) axis appear to be involved early in CDR1 and do not require the physical loss of cells as a decision point indicated by the "I" for "information" in Fig. 1.

Organisms have the capacity to mount a similar metabolomic response to stress, regardless of whether the triggering event is neuropsychiatric (Picard et al., 2015), or physical cell damage (Nishi et al., 2013). In both cases, mitochondria are the pivotal organelle (Picard et al., 2017). In both cases extracellular ATP is released by stressed cells as a first alarm for entering CDR1 and the healing cycle (Fig. 1) and intracellular calcium handling is regulated (Schmunk et al., 2017). When glucocorticoids are directly released by ATP stimulation of the adrenal cortex by stressed or damaged cells, hypothalamic corticotrophin releasing factor (CRF) and pituitary ACTH are decreased by feedback inhibition. On the other hand, childhood or adult neuropsychological stress can lead to direct stimulation of CRF. In addition to CRF receptors in the brain, peripheral CRF receptors exist in the GI tract and other organs (Buckinx et al., 2011). Peripheral metabolic responses to stress appear to be regulated in part by urocortin acting on peripheral CRF2 receptors in the kidneys and GI tract (Lovejoy et al., 2014). Drugs and supplements directed at NRF2 or CRF2 signaling may have broad reaching effects since they will affect the entry and completion of the earliest stage of the cell danger response (Fig. 1, Table 2).

HIF1α (hypoxia induced factor 1α), mTOR (mammalian target of rapamycin), and the arylhydrocarbon receptor (AhR) are important for CDR2 associated cell proliferation (Figs. 1 and 2, Table 2). Because CDR2 involves cell growth and proliferation, the risk for side effects and iatrogenic complications of CDR2 modulating therapies is high. The drug 1,4 DPCA has been used to target proline hydroxylase domain (PHD) proteins. By inhibiting PHDs, HIF1α is stabilized even under normal oxygen levels. This creates a metabolic state of pseudohypoxia and facilitates tissue regeneration after injury (Zhang et al., 2015).

mTOR and its partners are needed to help coordinate anabolic cell growth. Phosphatidic acid that is newly synthesized from fatty acids

Table 3
Stress-response systems regulated by the mitochondrial CDR.

No.	Stress response system	References
1	Apoptosis and anti-apoptosis	(Portt et al., 2011)
2	NRF2 activation	(Esteras et al., 2016; Naviaux, 2012)
3	Sirtuins and epigenetics	(Lin et al., 2018)
4	Scar formation	(Kuehl and Lagares, 2018)
5	Autophagy	(Boya et al., 2018)
6	Mitophagy	(Zimmermann and Reichert, 2017)
7	Exosomes and secretion	(Claude-Taupin et al., 2017; Saeed-Zidane et al., 2017)
8	Lipid raft formation	(Sorice et al., 2012)
9	Efferocytosis	(Wang et al., 2017)
10	Endoplasmic reticulum (ER) stress	(Carreras-Sureda et al., 2018)
11	Proteostasis and the unfolded protein response	(Murao and Nishitoh, 2017)
12	Transglutaminase activation	(Nurminskaya and Belkin, 2012)
13	DNA damage and repair	(Prates Mori and de Souza-Pinto, 2017)
14	Sensory processing	(Kann, 2016)
15	Allodynia, fibromyalgia, chronic pain	(Gerdle et al., 2013)
16	Hypothalamic-Pituitary-Adrenal (HPA) axis	(Lapp et al., 2018)
17	Liver xenobiotic detoxification	(Jeske et al., 2017)
18	Renal tubular secretion and reabsorption	(Kim et al., 2012)
19	Autonomic nervous system dynamics	(Ford et al., 2015)
20	Innate immunity, inflammation, allergies, autoimmunity	(Hoffmann and Griffiths, 2018; Mills et al., 2017)
21	Energy, glucose, and lipid metabolism	(Anupama et al., 2018)
22	Hypertension and cardiovascular stress responses	(Lahera et al., 2017)

and glycerol 3 phosphate, binds mTOR, alters metabolism, and stimulates growth (Menon et al., 2017). Rapamycin and other mTOR inhibitors have antiproliferative and immunomodulatory effects and have been used to treat a mouse model of a mitochondrial disease called Leigh syndrome (Johnson et al., 2015), but side effects like delayed wound healing, stomatitis, hypercholesterolemia, and susceptibility to viral infections, may complicate broad extension to CDR related chronic diseases in humans.

The AhR connects many pathways in CDR2. These include effects on redox signaling and HIF1α, circadian rhythm regulation through BMAL, and immune function via T_{reg} cells (Gutierrez Vazquez and Quintana, 2018). Indoles from food and the microbiome, and kynurenine from the inflammatory arm of tryptophan metabolism, are natural ligands for the AhR. These effectors act through AhR to facilitate anti inflammatory T cell and macrophage responses to prevent runaway inflammation during CDR2.

The differentiated functions of cells begin to appear again as cells leave the cell cycle of CDR2 and enter CDR3 (Figs. 1 and 2). Cells become integrated intro the extracellular matrix and 3 dimensional structure of tissues once they have stopped growing in CDR3. Genes important for CDR3 function include AMPK (AMP activated protein kinase), PPARs (peroxisome proliferator activated receptors α, β/δ, γ), RXRs (retinoid × receptors), BCL2, iron sulfur cluster proteins, FXR (farnesoid × receptor; also called the BAR: bile acid receptor), and mitochondrial fusion proteins (Table 2). The literature on each of these genes and gene families is extensive. Each plays a role in facilitating mitochondrial polarization from M0 and M1 in CDR2 to M2 organelles adapted for oxidative phosphorylation and the beginnings of metabolic complementarity and differentiated cell function in CDR3 (Fig. 2).

19. Dangers of tonic, single-stage, CDR interventions

Many drugs have mitochondrial toxicity (Will and Dykens, 2018). These drugs can benefit some people, but lead to catastrophic side effects in others. Predicting the mitochondrial risk has proven difficult. The reason for this may lie in the fact that different drugs target mitochondrial functions in different stages of the healing cycle. Visualization of the healing cycle permits a conceptual understanding of how these drugs and certain genetic polymorphisms called ecoalleles (Naviaux, 2017), can have a beneficial effect on one class of aging related disorders, while having a detrimental effect on others. For example, mitochondrial DNA variants that increase the risk of Parkinson disease (a CDR3 associated disease) also decrease the risk of prostate cancer (a CDR2 associated disease). This amphitropic effect of CDR selective factors is seen in both genes and drugs. It is likely that chronic treatments directed at any one of the checkpoints governing the healing cycle, will increase the risk of disease caused by unbalanced accumulation of cells in another stage of the CDR. For example, certain treatments of cancer (a CDR2 disease) will increase the risk of Alzheimer dementia (a CDR3 disease) (Driver, 2014). Or a treatment for cardiovascular disease and hypertension (CDR2 disorders) will increase the risk of autoimmune disorders (CDR3). Evidence for this includes data on statin associated polymyalgia rheumatica (de Jong et al., 2012), and drug associated Lupus. Likewise, it is theoretically possible, although not yet demonstrated, that chronic preventive therapy for dementia (CDR3), will increase the risk of certain cancers (CDR2) by decreasing excitotoxicity and the removal of mutant cells by immune surveillance. Chronic treatments for pain and inflammation syndromes associated with CDR1 disease may increase the risk of diabetes and cardiovascular disease (CDR2 assoicated disorders), and/or autoimmune disease (CDR3 associated disorders) (Chang and Gershwin, 2011). Subdivisions within each of the CDR stages are likely to exist. For example, the fact that statin treatment for cardiovascular disease increases the risk of diabetes (Chrysant, 2017) suggests that these two disorders belong to functionally separate subdivisions within CDR2 (Table 1, Fig. 2). Further resolution of subdivisions within each stage of the CDR, and corrections of any errors in this first version of the model will require future research. However, without an understanding of the pathophysiology of the healing cycle (Figs. 1 and 2), there is no unified framework for predicting the complex side effects of old and new treatments for chronic disease.

20. Evolutionary origins

It is no accident that the stages of healing recapitulate the chemical evolution of animal cells. The Precambrian Earth had an atmosphere that was largely devoid of oxygen. When capillaries, lymphatics, or glymphatics in the brain (Plog and Nedergaard, 2018) are torn by injury or decreased by disease, oxygen delivery and waste removal are impaired. An alternative method of energy production must occur if cells experiencing hypoxia are to survive. Under conditions of impaired oxygen delivery, oxidative phosphorylation is handicapped and glycolysis becomes a more reliable source of energy. Once the damage is contained, aerobic glycolysis provides a way of removing excess oxygen, which is genotoxic, to protect against DNA damage, while permitting rapid cell growth needed for biomass replacement. This patterned sequence of metabolic transitions needed for orderly wound repair, tissue regeneration, and differentiation has been studied recently in a classic model of healing and regeneration in flatworms (*Planaria)* (Osuma et al., 2018).

21. Allostasis and the mitochondrial nexus

Allostasis is a concept that was introduced in the late 1980s by Sterling and Eyer (Sterling and Eyer, 1988). The authors gave credit to Professor Charles Kahn at the University of Pennsylvania for suggesting the term. Allostasis literally means “stability through change”. Brain control of metabolism was a fundamental principle described in this paper. Allostasis embodied the idea that all body functions need to be adjusted dynamically according to continuously changing environmental conditions to achieve maximum fitness for long term survival

and reproduction. While the concept of "homeostasis" taught in medical schools today describes the idea that every measureable parameter in the body has an "optimum set point" that is continuously defended based on local signals, allostasis points out that all physiologic parameters vary within large dynamic limits according to recent, current, and anticipated future environmental conditions based on brain coordination of the needed physiologic adjustments.

The range of variation for any given parameter is very large in the young, but the capacity to achieve the same dynamic highs and lows decreases with age. This decline is associated with an age related decrease in the physiologic reserve capacity of every organ system. In an example given by the authors, when blood pressure was measured continuously for 24 h in a young man, values of 110/70 were maintained for several hours during the day. It dropped to 90/55 for an hour when he fell asleep during a lecture. Preparing for work in the morning produced a value of 140/80 for 2 h, while dropping to 70/40 for 6 h at night during sleep, and to 50/30 for 1 h during deep sleep (Sterling and Eyer, 1988). The point of allostasis is that each of these blood pressures is "normal" for the conditions during which they occurred. Over time, if higher blood pressure is maintained, the smooth muscle lining of blood vessels becomes thickened and even higher blood pressures are required to maintain the same resting blood flow. Sterling and Eyer point out that under conditions of unpredictable environmental stress, the brain becomes "addicted" to systems and signaling molecules (hormones, neurotransmitters, cytokines, and metabokines) needed to produce rapid arousal states, and the anticipatory stress responses become the norm. This complicates treatment. Some therapies can result in "withdrawal" symptoms, making a return to a healthy ground state difficult to maintain without a persistent change in diet and lifestyle.

McEwen and Stellar introduced the concept of allostatic load (AL) in the early 1990s (McEwen and Stellar, 1993). Under this concept, when homeostasis fails in the face of multiple types of environmental stress, many different types of disease can result. Recent multivariate analysis of 23 measurable parameters, reporting on 7 physiologic systems that regulate the stress response concluded that AL was a valid construct for operationalizing the components of variance contributed by many different stressors (Wiley et al., 2016). Interestingly, all the metabolic, inflammatory, neuroendocrine, and gene expression changes that occur in response to stress are regulated by mitochondria (Picard et al., 2015). McEwen and coworkers have recently incorporated the idea of mitochondria as the nexus for regulating the biomarkers of AL and chronic disease (Picard et al., 2017). Mitochondria help coordinate the large majority of stress response systems that become activated by allostatic load (Table 3).

Under the healing cycle model for chronic disease, allostatic load initiates the CDR and the healing cycle. In most cases of persistent chronic illness lasting for > 3 6 months, mitochondria are not dysfunctional. They are just stuck in a developmental stage that was intended to be temporary, unable to complete the healing cycle. The healing cycle requires a *programmed change* in mitochondrial function a shift from M2, to M1, to M0 organelles, and back to M2 (Figs. 1 and 2). When the programmed change becomes fixed and is unable to cycle normally, chronic illness results (Table 1). Over time, sustained changes in mitochondrial function can lead to structural changes in tissues and organs that can make full recovery more difficult.

22. The dauer failsafe response in humans ME/CFS

Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is an energy conservation program a suite of metabolic and gene expression changes that permits persistence under harsh environmental conditions at the expense of reduced functional capacity, chronic suffering, and disability (Naviaux et al., 2016). A formal animal model for ME/CFS has not yet been developed. However, several energy conservation states are known that are activated by harsh environmental conditions. One of these is called dauer, the German word for persistence, or to endure. When dauer is triggered by harsh conditions, the life expectancy of a classical genetic model system, the 1 mm long worm *Caenorhabditis elegans,* is extended from 2 to 3 weeks to up to 4 months. Animals that fail to enter dauer under harsh conditions die at an increased rate. In this sense, the metabolic program activated by dauer is a failsafe mechanism that increases the chances of survival in a harsh and unpredictable environment.

Interestingly, the genes involved in inhibiting and promoting dauer have been a rich resource for the study of longevity (Uno and Nishida, 2016). Many DAF (dauer associated factor) genes are also regulated by caloric restriction, a common environmental stress known to increase life expectancy in mammals and many other animals. Despite the fact that dauer worms live longer than unstressed animals, it is not a fully functional life. Mitochondria polarize toward a hardened M1 configuration that is adapted for inducible reactive oxygen species (ROS) production, metabolic energy production shifts toward increased usage of glycolysis, which allows dauer animals to survive in reduced oxygen environments (Hand et al., 2011). Some fatty acid oxidation is still conducted by the newly polarized mitochondria to permit stored fat reserves to be used for energy, while peroxisomes use very long chain fatty acids to synthesize a glycolipid pheromone (a daumone) needed to induce and maintain the dauer state (Joo et al., 2009). Behavioral responses become "brittle", such that small stimuli produce large responses in otherwise docile animals. Dauer animals are also more resistant to cold stress (Hu et al., 2015), ultraviolet (UV) light (Murakami and Johnson, 1996), and salt stress. Significant changes in circadian rhythm regulation (Driver et al., 2013), innate immunity (Holt, 2006), behavior (Lee et al., 2017), and sensory processing (Chen and Chalfie, 2014) also accompany the dauer phenotype. Overall, the dauer state and other hypometabolic states permit survival under harsh conditions, but at a high price of much altered and much restricted normal function.

The good news is that the dauer state in the worm model is completely reversible. If dauer is a good model for ME/CFS, then there is hope that by studying the molecular controls of the dauer phenotype, new treatments might be discovered rationally to help stimulate the exit from the dauer like state and begin the process of recovery. The following is a summary of a plausible sequence of pathogenesis for ME/CFS. All stressed cells leak ATP through stress gated pannexin/P2X7 and other channels. Extracellular ATP (eATP) signals danger and CDR1 is initiated (Fig. 1). If the acute cell danger response and healing cycle fail to eliminate the stress and stop the ATP leak by successful completion of CDR3, then an energy conservation program is activated. Normal cell activation pathways utilize lipid rafts and sphingolipid microdomains on the cell membrane to facilitate metabokine and cytokine receptor binding and signaling by receptor subunit dimerization. Sphingolipids are downregulated in most cases of ME/CFS (Naviaux et al., 2016) and may facilitate an energy conservation state.

The dauer like energy conservation program in mammals may also involve a ligand receptor desensitization process, decreasing the ability of cells to release intracellular calcium when needed. Calcium stimulates mitochondrial oxidative phosphorylation. When stimulated by ATP and related nucleotides, IP3 gated calcium release is decreased (Schmunk et al., 2017), and mitochondrial and whole cell reserve capacity is reduced. Other mechanisms for downregulating mitochondrial energy production can contribute to this energy conservation state. A multifactorial reduction in mitochondrial pyruvate dehydrogenase complex activity in ME/CFS has been described (Fluge et al., 2016). Upregulation of ectonucleotidases like CD39 and CD73 can increase the conversion of ATP and ADP to AMP and adenosine. Both AMP and adenosine bind adenosine receptors (Fig. 4A) and produce a reversible hypometabolic state in mice that is protective against many environmental stresses, including lethal irradiation (Ghosh et al., 2017). Continued leakage of ATP to the extracellular space for CDR signaling also creates a source for the hypometabolic signaling molecules AMP and adenosine, while depleting intracellular reserves of ATP. Although not

yet tested in a clinical trial in patients with ME/CFS, the ATP and UTP leak might be stopped by blocking the efflux of nucleotides through the pannexin/P2X7 channel with an antipurinergic drug, thereby un blocking the healing cycle (Fig. 1) and permitting recovery to begin. This is similar to a strategy recently tested in a clinical trial in autism spectrum disorder (Naviaux et al., 2017) and illustrated in a whiteboard animation available at: https://www.youtube.com/watch?v=zIdUufy8Lks.

23. Reversibility of chronic illness

If a chronic illness occurs because of a change in function associated with blocks in the CDR, and not a change in structure or loss of cells, that illness is theoretically reversible, ie, curable. When the healing cycle is unblocked, a full recovery is possible. Because the path leading to healing and recovery is different from, and not the reverse of the path that led originally to the disease (Fig. 3), the term “reversibility” is technically incorrect. This point is expanded in Section 29 below. Even when there is some cell loss, scarring, calcification, or other structural change, some healing is still possible by tissue remodeling, but a full recovery becomes more difficult to achieve. Autism spectrum disorder (ASD) can be classified as a CDR3 disorder (Table 1), characterized by both functional and brain structural changes that can vary significantly in severity. In a mouse model of autism, when treatment was delayed until the human biological age equivalent of 30 years old, the core functional abnormalities in behavior and metabolism in ASD could still be completely corrected with antipurinergic therapy (APT) with sur amin, but the gait abnormalities associated with the structural loss of cerebellar Purkinje cells were not reversed (Naviaux et al., 2014).

In the case of cancer, cardiovascular disease, and other proliferative disorders associated with CDR2 diseases (Table 1), metabolic, innate immune, and adaptive immunity can reduce the burden of abnormal cells by removing them. Successful reactivation of CDR1 in the sur rounding normal cells, followed by entry into CDR2 for biomass re placement and CDR3 to facilitate tissue remodeling, may result in functional cures for the major symptoms of some CDR2 disorders, even if some limitations remain because of imperfect biomass replacement and tissue remodeling. In the case of CDR3 diseases like autism, treat ments directed at unblocking the healing cycle and rebooting metabo lism may lead to remarkable clinical improvements (Naviaux et al., 2017).

24. The tempo of physiologic change

The tempo of chronic disease is slower than many people might think. Like a new exercise program, and shifts in metabolism after making an abrupt change in diet, new metabolism and physiology take at least 3 weeks in young adults to settle in to the “new normal”. The temporal parallel between disease, diet, and exercise is no accident. The ability to shift metabolism according to seasonal changes and new patterns of food availability within a few weeks of migration to a new location was key to the survival of our ancestors. This timing is built into our genes. It takes 3 4 days before new patterns of gene expression begin to consolidate, and about 3 weeks for new physiologic patterns to “reset” to a new normal after a change in diet, exercise, and other en vironmental conditions. It takes more time to fully commit to the change. Ultimately, it takes a season of about 3 months or more to fully commit to new foods, physical activities, and environmental exposures (sun, monsoons, droughts, hard freezes, etc) of the season. Three months is also the average minimum time needed to demonstrate sy naptic remodeling with exercise or meditation (Thomas and Baker, 2013). A similar tempo might be needed to “reboot” and reset meta bolism to a new normal after starting a new treatment for a chronic disease.

25. Metabolic addiction

Once the CDR is unblocked and the healing cycle rebooted, the simplest form of the CDR model predicts that recovery will follow naturally, and health will persist because the genes inherited from our ancestors will defend health in preference to disease and disability. Clinical experience suggests this is not always true. Many patients tend to drift back to the old disease state unless they continue to take measures to actively prevent relapse. This phenomenon may be meta bolically similar to addiction. Addiction is a physiologic condition characterized by a baseline physiologic arousal or anxiety state that is temporarily quenched or relieved by a particular behavior or drug. A large body of research has shown that the predisposition to addiction is conditioned by genetics, epigenetics, environmental chemicals, and life stress (Yuan et al., 2016). The most successful alcohol and drug re habilitation programs teach that recovery is a lifelong process. An ad dict is never “cured”. They are taught to identify themselves as a “re covering alcoholic” or “recovering gambling addict” for life to strengthen resilience and decrease the risk of relapse.

The concept of metabolic addiction suggests that the increased risk of relapse after recovery from chronic illness is the result of a physio logic dependence on the endogenous chemical state produced by a particular stage of the CDR. For example, once a person has suffered from an episode of major depressive disorder (MDD) and recovered, the risk of recurrence is 3 6 times greater than the background population risk (Hoertel et al., 2017). This latent risk suggests that predisposing genetic and/or metabolic factors persist that facilitate a drift back to chronic illness, even after predisposing environmental risks are re moved. New studies using metabolomics methods will be needed to test this hypothesis directly.

26. The brain controls metabolism and exit from the CDR

The last step in the healing cycle, CDR3, is ended when the brain re establishes bidirectional neuroendocrine and autonomic communica tion with each organ system. Only after the brain re integrates meta bolism over the periodized course of wakeful activity and restorative sleep can the health cycle be re established. The vagus nerve plays and important role in communicating information from tissues to the CNS. Vagal mechanoreceptors and chemoreceptors monitor organ physiology (Powley et al., 2011). Eighty percent of vagus nerve fibers are made up of sensory fibers returning information from all organ systems to the brain. Among the chemoreceptors are vanilloid (TPRV1) and the pur inergic P2X3 receptors responding to noxious stimuli, and extracellular ATP, respectively (Hermes et al., 2016). Vagal afferents terminate in excitatory glutamatergic synapses in the *nucleus tractus solitarius* (NTS). From the NTS, extracranial sensory information is transduced and dis tributed widely throughout the brain. NTS fibers project back to the ventral vagal complex of the *nucleus ambiguus* and the dorsal vagal complex of the dorsal motor nucleus of the 10th cranial nerve (DMNX) as feedback to the vagus. Feedback to the *nucleus ambiguus* modulates signals conducted along myelinated motor fibers to the vagus nerve for rapid changes in cardiorespiratory and vasomotor function, swal lowing, speech, and hearing that occur with stress and well being (Porges, 2011). The NTS also projects to the locus coeruleus in the re ticular activating system to regulate behavioral responses to stress and panic, and to the amygdala in the limbic system, and the para ventricular nuclei of the hypothalamus to regulate physiologic and neuroendocrine responses to stress.

Brain neuroendocrine and autonomic systems function as bidirec tional circuits. When CDR stages 1 and 2, or the first parts of CDR3 are active in the periphery, this information is carried to the brain along three channels; endocrine feedback, autonomic afferents, and chemo sensory neurons. When this information is received, the brain initiates sickness behavior and sends pro inflammatory, pro stress, pro arousal endocrine and autonomic efferent signals to the periphery. Sleep

structure is also altered to facilitate recovery and promote survival. The default state in both the brain and peripheral tissues is CDR activation. In the absence of additional information, danger and threat are assumed. Healing is an active process that requires positive reinforcement with non danger, safety and security signals from the brain. Brain inflammation can last for a lifetime after physical injury (Johnson et al., 2013) or early life stress (ELS) and psychological trauma (Cameron et al., 2017). In addition, peripheral pain syndromes and organ inflammation are common after brain or spinal cord injury (Irvine et al., 2018) or brain death (Esmaeilzadeh et al., 2017; Jafari et al., 2018). Unresolved CDR activation by adverse childhood experiences (ACEs) and socioeconomic factors may also play a role in many other adult illnesses like heart disease, cancer, and stroke (Cassel, 1976; Hughes et al., 2017). Once the CNS efferent and local tissue CDR signals are effective, metabokines in the blood return to normal, cell danger signals diminish, and non danger, pro resolving, and pro healing signals predominate.

Metabokines like purines, pyrimidines, amino acids, bioamines, fatty acids, eicosanoids, sphingolipids, phosphatidic acids, lysophospholipids, and many others, in addition to critical blood chemistry information like sodium and osmolality are independently monitored by chemosensory neurons in the 8 circumventricular organs (CVOs) of the brain (Siso et al., 2010). These chemosensory neurons lack a blood brain barrier and provide continuous sensory information that is independent of endocrine feedback and autonomic afferents. One of the well known CVOs is the *area postrema* (AP) located at the floor of the 4th ventricle that contains the chemoreceptor trigger zone and regulates nausea and vomiting. The AP sends fibers that project to the *nucleus tractus solitarius* (NTS) to modulate the response to vagal sensory information (Hay and Bishop, 1991). Once blood chemistry starts returning to normal, chemosensory neurons of the CVO system communicate this information to neuroendocrine and autonomic systems to gradually shift efferent information back to anti inflammatory, anxiolytic, pro resolving, and pro social signals. This shift in outflowing information from the brain marks the last stages of CDR3 and is required for re entry into the health cycle of wakeful activity and restorative sleep (Fig. 1, Table 2).

27. Deterministic health and stochastic disease

While it is not possible to predict when and how an injury will happen, the chance that injuries and infections will happen is a certainty for all life on Earth. Without a way to heal after these injuries, any species would go extinct. The genetic program that facilitates recovery from any injury has been highly selected and tuned over evolutionary time. We now know that the healing cycle activates discrete sets of genes in a predictable sequence after injury. While injury is random, recovery and health are deterministic. Recovery is the programed result of the healing cycle (Fig. 1). Recovery occurs in the large majority of cases when the healing cycle is activated. Yet, why is it that some individuals get sick from common exposures, and cannot complete the healing cycle? For example, Epstein Barr virus (EBV) is a risk factor for ME/CFS. In the US, 82% of people have been exposed to EBV by the time they are 19 years old (Dowd et al., 2013). If EBV is "the" cause, why do fewer than 1% of the US population have ME/CFS? Clinicians have documented dozens of other risk factors that can contribute to the chances of developing ME/CFS. An interesting point about chronic disease is that every non infectious, chronic illness is caused by a perfect storm of several factors, not by one factor. The chances that this perfect storm of factors for a particular disease will occur for any one patient in a population of millions is small. But once disease strikes, the small initial probability rises to 100% certainty for that person. Therefore, as the environmental factors like pollution and food chain contamination start to increase, more people are exposed to risk, and more individuals will develop chronic illness. Reducing the environmental factors that contribute to risk will reduce the incidence of chronic illness.

So is chronic illness deterministic or stochastic? Scientists are most comfortable with deterministic, linear chains of logic. If cause "A" leads to disease "B" in 100% of people exposed and disease "B" never occurs without an exposure to cause "A", then there is little room for debate. Cause "A" is necessary and sufficient to produce disease "B". The problem is that literally none of the top 10, non infectious chronic illnesses in the world has a single cause that produces the disease in every person exposed. Heart disease, diabetes, stroke, dementia, cancer, arthritis, autism, ADHD, depression, and schizophrenia all have dozens of risk factors, but no single "cause". By reducing the exposure to the risk factors, a nation can prevent a large percentage of all chronic illness in its citizens. Chronic illness is best modeled as a stochastic process, with an incidence that is modifiable by increasing or decreasing risk factors. This means that in large populations like the 325 million people in the United States, the management of even small chemical risk factors by a proactive government can produce dramatic changes in the incidence of chronic illness and its ripple effects in society. For example, if a hypothetical chemical were ubiquitous and synergized with the background mix of factors to increase the risk of mental illness leading to gun violence in just 0.001% of the population, removal of that chemical from the environment would result in 3250 (0.001% × 325 million) fewer cases of mental illness and gun violence each year.

28. A new pharmacology

In the past, student physicians and pharmacologists have been taught that drugs work by mechanisms that are the same in health and disease. While this was true for drugs designed to treat acute illneses, the treatment of chronic disease forces a revision of the old teaching. The health cycle and the healing cycle represent different biological states that have different bioenergetics, and different governing dynamics (Fig. 1, Table 2). *Biology* and *pathobiology* are qualitatively distinct states of function. Both are normal. However, the functional state associated with *pathobiology* (the healing cycle) is only normal when it occurs transiently. Pathological persistence of the stages of the healing cycle lead to chronic illness and the inability to heal. Drugs that will work best for treating chronic illness will target receptors like those illustrated in Fig. 5A that play key roles in the healing cycle, but remain virtually unused, or are used differently in health.

Personalized pharmacogenomics will help refine the new pharmacology as it has the old (Caudle et al., 2016), once the best targets in the healing cycle have been identified. A goal of the new pharmacology will be to discover new treatments for chronic illness that have targets that are active in disease, but are dormant in health, and therefore have little or no effect in healthy children and adults. Like Paul Ehrlich's magic bullet (Tan and Grimes, 2010), the new drugs will have fewer side effects because once the disease is cured and the patient has recovered, the target of the drug will have disappeared, and the bullet can pass without causing harm. The need for chronic drug use is then eliminated. While the simile is evocative, it is important to remember that "magic" bullets are not really magic. They just work by scientific mechanisms that have not yet been discovered, or are not yet well understood.

29. Failures of failure analysis

A fundamental difference between living and inanimate systems is that living systems can heal and inanimate systems cannot. When a machine or other manmade object of technology fails, the analysis of the mechanism of failure has proven to be a logical and effective way to discover a fix for the problem. For example, once the defect in the optics of the Hubble Space Telescope was precisely characterized, a solution was engineered to compensate for the defect, thereby fixing the problem. This same engineering logic is often applied successfully to "fix" acute illnesses in living systems. In contrast to acute illnesses, many

chronic disorders are self sustaining alternative performance or failure states that limit the potential for independence in a child and reduce the quality of life in children and adults for years.

New tools in systems biology like genomics, RNAseq, proteomics, and metabolomics have created the ability to minutely characterize the way a system has failed in any one of the complex disorders listed in Table 1. The same tools can be applied to individuals with any given chronic disease as part of a precision medicine effort to phenotype that patient at the molecular level. The results of this precision medicine analysis have shown that chronic illnesses are characterized by hundreds of molecular differences from healthy control states. Historically, the pharmaceutical industry has systematically analyzed the molecular paths that lead to a recognizable disease state and have cataloged the defects present once that disease state becomes persistent. This information was then used to identify drugable targets. This approach to treat chronic disease in living systems has failed to produce cures because it is more like engineering than biology. Living systems engage the same evolutionarily conserved path to cellular recovery after injury the same healing cycle with minor modifications regardless of the mechanism of injury (Fig. 1). Biological healing in a living system does not involve the precise identification and point for point correction of each of the hundreds of defects present in chronic illness. Living systems do not turn back the arrow of time to retrace the path that led to the injury and illness. They move forward along a new path in order to heal (Fig. 3), eliminating hundreds of abnormalities in step with progress through each stage of the CDR. Each step in healing represents a concerted regime change in metabolism and gene expression, like the rapid succession of cellular ecosystems that return the system back to optimum integrated performance. For these reasons, treating a unique target for each individual disease may not be necessary. The path that permits a patient to exit any given disease state, i.e., to recover from chronic illness, may be the same for hundreds of diseases. A new generation of drugs and devices designed to unblock the healing cycle may turn out to be able to treat many diseases. Only time, and good clinical trials, will tell if this hypothesis is true.

30. Conclusions

30.1. Beginning a 2nd book of medicine

Much of western medical teaching in the US in 2018 is based on principles that were developed historically to treat acute illnesses from poisoning, physical injury, and infections. These principles have been incorporated into the books and literature used to train modern physicians and health care workers. Philosophically, this corpus of knowledge can be thought of as "the 1st book of medicine". When treatments developed to treat acute causes and specific organ system dysfunction are applied to chronic illness, they produce marginal improvements, almost never cure a chronic disease, and must be given for life. This is good from the point of view of a drug company that manufactures a drug, but not for patients, and not for a nation whose economic health is tied to the health of its citizens.

Healing is a biologically active, energy requiring process that is intrinsic to all life. Healing chronic illness cannot occur without engaging, unblocking, and actively supporting this universal system. "The 2nd book of medicine" will focus on the prevention of chronic illness and the care and recovery of patients with chronic disease. This book will introduce the concept that many treatments for chronic illness will be directed at the processes that block the healing cycle. These new treatments may only need to be given for a short period of time to cure or improve a chronic illness. This might be functionally similar to applying a cast to promote the healing of a broken leg. Treatment only needs to be given for a period of time needed for tissues to complete the healing cycle. When the cast is removed, the limb is weak, but after a period of time needed for reconditioning, the muscles have recovered, and the bone that was once broken is actually stronger at the point of injury than it was before. New drug treatments for chronic disorders like autism or PTSD, may only need to be given for a few months at a time, until the healing cycle can be completed, or the process of recovery, building strength, fitness, and resilience can be started and become self sustaining again. Individuals may need occasional "tune ups" to maintain recovery over the years, since genetic predispositions, environmental conditions, and metabolic memories of past exposures may cause health to drift back to the previous disease pattern, but the majority of time might be spent without the need for chronic treatment, or the limitations caused by chronic illness.

30.2. Potential economic impact

Eighty six percent (86%) of the $3.3 trillion spent annually on medical costs in the US is spent to care for chronic conditions (CDC.gov, 2017). The cost of health care is predicted to rise to $5.5 trillion by 2025 because of chronic disease. This will require nearly 20% of the GDP of the US, estimated to be about $27 trillion (CMS.gov, 2017), if the trend of relentlessly growing chronic disease is not reversed. Today, 30% of children under 12 years have a chronic disease, and another 20% will develop a serious mental illness in their teens (HHS, 2018). Sixty percent of adult US citizens 18 64 years have a chronic disease, 90% of people over age 65 have at least one chronic illness, and 81% over 65 have 2 or more chronic conditions (CDC.gov, 2017). Shifting healthcare insurance policies from multi payer to single payer or back will have little effect on this cost. The fact that more Americans are getting sick, and not small variations in insurance policies, is driving the lion's share of rising costs. If just 10% of people now suffering with chronic illness could be cured by new methods directed at the healing cycle, more than $250 billion (10% × $2.5 trillion) would be saved annually. The savings in a single year would be more than the annual budgets of the National Institutes of Health (NIH; $37 billion), Environmental Protection Agency (EPA; $8.7 billion), Food and Drug Administration (FDA; $5.1 billion), and the US Department of Agriculture (USDA; $151 billion) combined.

31. Summary

Interruptions in the molecular stages of the healing cycle may be at the root of many complex, chronic illnesses. Three stages of the cell danger response (CDR1, 2, and 3) comprise the healing cycle. These stages are triggered by stress or injury and controlled by changes in mitochondrial function and metabolism (Figs. 1 and 2, Table 2). Many metabolites are metabokines that bind to dedicated receptors and signal when a cell is ready to enter the next stage of healing (Figs. 4 and 5). Purinergic signaling from the release and metabolism of extracellular nucleotides plays an important role in all stages of the healing cycle (Fig. 1). Programmed changes in the differentiation state of mitochondria, known as M0, M1, and M2 polarized organelles, and corresponding changes in cellular redox and the repurposing of cellular energy for cell defense and healing, also play fundamental roles (Fig. 2, Table 3) (Naviaux, 2017). When a stage of the healing cycle cannot be completed, dysfunctional cells accumulate that contain developmentally inappropriate forms of mitochondria, organ function is compromised, and chronic illness results (Fig. 3). Over 100 chronic illnesses can be classified according to the stage of the CDR that is blocked (Table 1). Unblocking therapies directed at stimulating the completion of the healing cycle by regulating metabokine signaling hold promise as a new approach to treatment. A small clinical trial of the antipurinergic drug suramin in autism spectrum disorder (ASD) has shown promise for this approach (Naviaux, 2017; Naviaux et al., 2017). Metabolic addiction to the chemistry produced by different stages of the CDR can occur. When this happens, it can create a life long risk of relapse or slow return to chronic illness if diet and lifestyle interventions are not maintained.

Prevention and treatment of chronic illness require distinctly

different, but complementary approaches. New cases of chronic illness can be *prevented* by reducing the environmental risks that trigger the damage cycle of the CDR, and by promoting exercise, nutritional and life style changes that promote resilience and maintain the health cycle (Fig. 1). However, once illness has occurred in a given patient, the opportunity for prevention is lost, and a perfect storm of multiple triggers can usually be identified. Many triggers are remote and no longer present. Once any remaining triggers have been identified and removed, and any symptoms or primed sensitivities caused by the metabolic memory of those triggers have been treated, a new approach to *treatment* is required to improve the chances of completing the healing cycle and achieving a full recovery. By shifting the focus away from the *initial causes*, to the metabolic factors and signaling pathways that *maintain* chronic illness by blocking progress through the healing cycle, new research will be stimulated and novel treatments will follow.

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Conflicts of interest

RKN is a scientific advisory board member for the Autism Research Institute and the Open Medicine Foundation, and has submitted a pa tent application for the use of antipurinergic therapy in autism and related disorders.

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From: Jayne [redacted]
Sent: Friday, 28 June 2019 10:05 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern,

I am horrified to read of the proposed changes to regulations permitting doctors to incorporate integrative and complementary medicine into their practices when warranted. These regulatory changes must not be allowed to occur.

Like many other Australians, I actively choose GPs with complementary and integrative medicine knowledge to care for my health and that of my family.

Complementary medicines are low risk and are usually inherently safer than pharmaceutical and surgical options, so should always be our first line of preventive healthcare and the first consideration when treating minor ailments. They also provide valuable support for patients' experiencing chronic healthcare problems.

Making it more difficult for people to access the natural and complementary medicines that they prefer denies them access to safe treatments under the professional supervision of their doctor.

Furthermore, consumers who are looking for complementary and integrative options won't stop using them if their doctor is no longer able to prescribe them. Instead, they'll seek guidance from someone less qualified or choose to treat themselves without any professional oversight at all - so the proposed regulatory changes have the potential to be harmful to the health of many Australians.

Natural and integrative medicines are increasingly backed by scientific research. That evidence base is growing exponentially and will only continue to do so in the future, and the ability of professionally trained doctors to evaluate that evidence and use it to make choices for their patients should not be jeopardised. To claim that these forms of medicine are 'unconventional' or 'emerging' is to ignore the reality of both the evidence base, and in some cases the centuries of traditional use and empirical data that supports their use.

Please, for the sake of all Australians, do not allow this regulatory change to proceed. As a community, we should be investing in research into complementary medicines and actively educating doctors to ensure it becomes increasingly integrated into standard medical care.

Yours sincerely,
Jayne Tancred

From: [redacted]
Sent: Saturday, 13 April 2019 11:44 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments'

To Whom it May Concern,

My name is Isabelle Taye and I am a qualified naturopath who has been practising in north-western Sydney for the past 11 years.

Having completed both a Bachelor's Degree in Health Science (Comp Med) through Charles Sturt Uni as well as attaining Advanced Diplomas in Naturopathy, Functional Nutrition, Western Herbalism more than a decade ago, I am now furthering my passion for natural health and its scientific validation by undertaking a Master's in Health Science by Research through Southern Cross University. It is from this deep respect of both natural medicine and modern science that I wish to address the latest consultation document regarding complementary and unconventional medicines.

With the rise of natural medicines and the wealth of (mis)information now available to the public it is utterly vital that qualified healthcare practitioners who specialise in both conventional and natural medicines are allowed and encouraged to educate the public and encourage the use of products that have been made to meet the stringent requirements set out by the TGA. To that end, I believe that the current Code of Practice already addresses all safety and efficacy issues related to Integrative Medicine.

By undertaking more restrictions on qualified and experienced health care professionals, the public is put at risk as not only will self-diagnosis and medication take place, patients will fail to disclose to their practitioners what other supplements they may be on resulting in potential adverse consequences. Having Integrative Doctors is most definitely in the best interests of both the public and the AMA.

I would hope that the board retains the current status quo regarding expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

Should you wish to contact me to discuss this further my phone number is [redacted] and my email is [redacted]

Thank you for your time and best wishes,

Isabelle Taye B.H.Sc (Comp Med), ND, JP

A: [redacted]
T: [redacted]
E: [redacted]
W: [redacted]

From: heather taylor [redacted]
Sent: Monday, 13 May 2019 8:49 PM
To: medboardconsultation
Subject: Do not limit my choice of therapy or practitioner

I have consulted both conventional and alternative therapists to maintain and improve my state of health and well being all my adult life. I wish to continue this positive practice and expect my right to choice be respected.

Thank you for listening to all people, and respecting their right to choice.

From: [redacted]
Sent: Saturday, 8 June 2019 10:40 AM
To: medboardconsultation
Subject: New guidelines

I strongly oppose the new medical guidelines surrounding 'complementary and unconventional medicine and emerging treatments' for many reasons including:

- The grouping of integrative medicine with 'unconventional medicine' and 'emerging treatments' may create the impression of being "fringe" rather than evidence-based
- That many of the terms used in the rationale such as 'unconventional medicine', 'inappropriate use' and 'emerging treatments' leads to ambiguity and uncertainty
- That the term 'complementary medicine' also includes access to traditional medicines
- No evidence produced in the discussion paper quantifies risk in practicing complementary or integrative medicine vs 'conventional' medicine
- That there was NO consultation with the Integrative Medicine or complementary medicine community before the document's release
- That the current Good Medical Practice: A Code of Conduct for Doctors in Australia already adequately regulates doctors' practise and protects patient safety. There is no need or justification for a two-tiered approach
- That the right of patients to determine their own medical care is under threat
- That the lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion which results in troublesome complaints

Please do not go forward with implementing these new guidelines as myself and my family will be heavily affected in many negative ways.

Regards,

J. Taylor

From: [redacted]
Sent: Wednesday, 3 July 2019 12:35 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Subject: Consultation on complementary and unconventional medicine and emerging treatments

I choose Option 1 for all the reasons stated therein.

Humanity is comprised of unique, autonomous individuals; each a product of blended, inherited traits, together with contemporaneous lifestyle, ideological and cultural constraints and choices.

The respect afforded the medical profession is founded on the fact that its members subscribe to non-maleficence via the Hippocratic Oath to "abstain from all intentional wrong-doing and harm" and to "neither...administer a poison to anybody when asked to do so, nor...suggest such a course." More particularly, in accordance with the Declaration of Geneva (WMA, 2006), medical practitioners also vow to "maintain the utmost respect for human life" and "NOT use...medical knowledge to VIOLATE HUMAN RIGHTS and CIVIL LIBERTIES, even under threat."

For the record:

Definition: HUMAN RIGHTS
"The basic rights and freedoms that all humans should be GUARANTEED, such as the right to LIFE AND LIBERTY, FREEDOM OF THOUGHT AND EXPRESSION, and EQUALITY BEFORE THE LAW";

and,

Definition: CIVIL LIBERTY
"FUNDAMENTAL INDIVIDUAL RIGHT PROTECTED BY LAW and expressed as IMMUNITY FROM UNWARRANTED GOVERNMENTAL INTERFERENCE"

Therefore, the medical profession cannot concomitantly condone unquestioning adherence to the seemingly limitless, admitted contraindications of the many treatments which can lead to further injury, disability and even death.

A system that is rewarded for recommending blanket treatments without including the beneficence of suitable, individually-tailored complimentary treatments and lifestyle changes could be perceived as unprincipled and provably dedicated to the extrapolation of the very issues it is commissioned with remediating, and has only limited success in 'curing'. Such a system would be accurately defined as dysfunctional and predatory in nature.

The Medical Board of Australia's myopic, ill-informed pursuit to outlaw integrative medicine, can be rightly construed as the unapologetic misappropriation of its authority in order to subvert justice to its own highly discriminatory and self-serving ends. It is riding rough-shod over the very ethical standards, i.e. human rights and civil liberties, its members have vowed to uphold.

It is therefore strenuously recommended that the Medical Board of Australia cease and desist from its hubris in the reckless pursuit to discredit and destroy the public's right and freedom to access integrative medicine.

Yours sincerely,

Lesley Taylor

Dr Margaret E Taylor
[redacted]

Consultation on complementary and unconventional medicine and emerging treatments.

Questions for consideration

The Board is inviting feedback on the issues and options outlined in the discussion paper.
My answers are in italics.

1. Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'?
If not, what term should be used and how should it be defined?

No, they are 3 different terms and describe 3 different types of practice and should not be lumped together as it confuses the issues.

2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice,[4] medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.'
If not, how should it be defined?

No, this definition is corrupted by trying to put a whole lot of practices together. It's impossible to link complementary medicine with either of the other terms.

3. Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'?

I think that the issues identified are real but are covered by the existing medical guidelines and that an additional range of regulations is unnecessary.

4. Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners that the Board has not identified?

Not that I know of.

5. Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'?

The same safeguards that are necessary for medical practice everywhere, ie reasonable evidence that the prescription or procedure is likely to help and informed consent. It's important to remember that pharmaceutical drugs and medical procedures are much more dangerous than nutritional supplements and herbs. Please see the enclosed graphic about Death risk in the UK and keep a sense of proportion about the relative danger to the public. Preventable medical injuries in hospitals and Adverse pharmaceutical drug reactions are much more likely to kill patients – NB this is a log scale.

6. Is there other evidence and data available that could help inform the Board's proposals?

I have heard the constant statements of the so-called Friends of Science in Medicine that there is no good evidence for many of these treatments, and I disagree. Whenever I hear of something that may be useful for my patients, I look it up on PubMed. Sometimes the studies are quite small but if the treatment is a simple one that is likely to be safe as it is part of the natural environment, eg a trace mineral, an N-of-one trial is often used in a reasonable dosage. This is a safe approach and many of the useful elements of modern medicine would not exist without careful trials in patients with observant doctors, for example lithium in bipolar disorder.
I enclose a very reasoned discussion of the extreme views of FOSM by conventional physicians including Professor Paul Komesaroff and others from the MJA 2012. There are several important points in the paper and I quote:

- *"That science should have a commitment to renunciation of the use of polemic and force to suppress contrary viewpoints.*
- *there is an extensive evidence base relating to other complementary therapies, including Western herbal products, nutritional supplements, traditional Chinese medicine, and certain non-drug practices, such as meditation.*
- *the concept of evidence-based medicine, which was once so popular, is highly contested and debated within Western medicine itself. Evidence from laboratory, epidemiological, clinical research and clinical trial studies cannot solely generate or determine the clinical decisions. These high-level data deal only with populations and probabilities and can, therefore, provide no more than hypotheses to be tested. It is the job of the clinician to convert these data into judgements relating to individual patients. Medicine is a complex craft, and a large part of its richness and success depends on its ability to draw on a wide array of practices and forms of knowledge. Despite the undoubted wealth of information that laboratory and population studies provide, from the point of view of the clinician, a great deal of uncertainty remains, at the conceptual and methodological levels. We cannot afford to be overconfident about our own approaches or dismissive of those of others."*

Options
7. Is the current regulation (i.e. the Board's *Good medical practice*) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?

Yes.

Also, although the FOSM group think that it is necessary to prevent people wasting their money on supplements and other natural remedies, our society allows people to legally waste money on harmful things eg alcohol, smoking, e-cigarettes, cars that go much faster than is safe to travel on roads, music that is so loud that it damages hearing, food full of sugar and fat, etc, etc. Is it really the job of the Medical Board to prevent doctors and other health practitioners taking part in a practice that is widespread and harmless compared to the dangers of pharmaceutical drugs and high technology medicine? (See the UK Risk of death graphic) The Board is doing an excellent job focussing on areas of medicine that are more dangerous to the general public, such as sexual abuse and people masquerading as doctors when they aren't. As an integrative doctor myself, I think it is important that we are

still guided by peer review and that it is necessary to have some restrictions on practices that are too extreme and I think the Medical Board is using the present guidelines effectively.

8. Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?

No, it will confuse the issue, as it will not be clear which of the two guidelines medical practitioners should follow. For example, if a GP prescribes omega 3 in fish oil to lower triglycerides, does that make them a complementary practitioner? The same rules should apply to all, and this will deal with the fact that new research becomes available over time and becomes mainstream at a later time and in between those 2 times, some doctors who are aware of and confident of the research will use it with growing confidence as more and more research becomes available. What if these guidelines had been operational in the years when Barry Marshall and Robin Warren were trying to prove that H Pylori was the cause of gastric ulcers. They had a lot of criticism of their hypothesis and it was years before it was fully accepted as conventional medicine and they won the Nobel prize for medicine. That was complementary/ emerging medicine until it was fully accepted by other doctors. How much evidence does it take to become conventional medicine? 5 studies? 10? 100? 2 meta-analyses? 5? You can see that it is impossible to clearly define the difference between conventional and complementary medicine so we have to rely on the integrity of the practitioner and the guidance of peers as the present system does, to keep reasonable bounds in medicine. There will always be a wide range of difference in doctors in their interests in new research vs old accepted ideas, and if this is stifled, the discovery of new treatments will be impaired.

Medicine and science must oppose intolerance and censorship

Friends of Science in Medicine should avoid threatening their own values

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BChineseMed(Hons), BA(Hons), PhD Student,[1] and Chinese Medicine Practitioner[2]

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Science has always been — and should be — a battleground for contending views on what is true. Because of the close connection between knowledge and power, however, the risk is always present that those who command the dominant theories or ideologies will rely on their positions of influence to overcome those who oppose them. It is important that those who treasure tolerance and the value of open, unfettered discourse remain sensitive to these risks and — even when they personally disagree — to protect and foster the expression of contrary viewpoints.

When the nature of science and medicine is at stake, the importance of this task is especially pressing. We believe that the views promoted in a commissioned editorial in the Journal, by the Friends of Science in Medicine (FSM), exceed the boundaries of reasoned debate and risk compromising the values that FSM claims to support.[1]

In its own words, the key objective of FSM is "countering the growth of pseudoscience in medicine", where true science is defined as a set of practices characterised by "an experimental, evidence-based approach". The strategy of the group — which deliberately and forcefully relies on the unquestioned eminence of its members — is to apply pressure on governments and educational institutions to withdraw or prohibit funding for health practices referred to in a general sense as "complementary medicines". The organisation models itself on similar groups in the United States and the United Kingdom and proudly refers to the success of these groups in having had funding removed from certain alternative medicine courses.[2] It is clear that FSM aims to emulate this success in Australia through a campaign to influence public opinion and apply pressure on government and educational institutions.

We do not write to advocate complementary medicines. Indeed, two of us are physicians who practise exclusively in the field of Western medicine and are actively engaged in "conventional" laboratory and clinical research. Furthermore, we accept that there are serious and important issues to be considered regarding claims about, and risks posed by, many "complementary" health practices, and regarding the nature and status of evidence in medicine. As even the most vigorous supporters of complementary medicines accept, the field has been beset by excessive and fraudulent claims, which in many cases have misled — and, in some cases, posed direct risks to — vulnerable individuals.

We feel that the appropriate response to these problems is not to seek to suppress all approaches to health care which we cannot understand or with which we do not agree. Rather, it should be to establish a system of safeguards that minimise risk, while continuing to protect the rights of consumers to choose their own health care practices. Such safeguards should include legal, professional and conceptual criteria and target specific rogue practices while protecting and regulating others. We believe that any approach other than this would run the risk of threatening the core values and practices of science and medicine.

What are the core values and practices of science? FSM claims that what distinguishes the "scientific" nature of medicine is its reliance on evidence, and that all other approaches to health care are merely "pseudoscience". We believe that this is wrong because it is at variance with the key insights of much of twentieth-century philosophy of science, which largely sought to understand the nature and meaning of science. There are many ways of defining what characterises science, but reliance on evidence is not one of them, because all systems of knowledge and belief make claims to interpretation of the evidence.[3,4] Indeed, it is well known that, in Galileo's day, Aristotelian physics commanded a much stronger empirical basis than did the esoteric theoretical idealisations of the Galilean system, not to mention Einstein's theories of relativity in the years after they were proposed.[5] Nor indeed is science merely a method, as it incorporates — and promotes — a wide array of methods and approaches.

What characterises the practices of science and medicine — as we understand and value them — is an openness to contrary perspectives and points of view, a belief in the merits of critical inquiry, a commitment to open and free dialogue to settle disputes and disagreements, and a renunciation of the use of polemic and force to suppress contrary viewpoints. We do not disagree with trenchant critiques of bodies of thought that cannot be substantiated by argument or data. What concerns us is a politicised process to apply pressure on governments and educational institutions to act in accordance with the views or convictions of one particular group.

In addition to this ethical point is a philosophical one. A key premise of many scientists and practitioners is that Western medicine is evidence-based whereas complementary medicine is not. There are several problems with this premise. First, as discussed above, is that it is mistaken to identify science with evidence. Second, the claim is based neither on evidence nor on a clear differentiation of the variety of forms of complementary medicines. While there may be little, if any, data to support more marginal, or fringe, forms of complementary medicines, there is an extensive evidence base relating to other complementary therapies, including Western herbal products, nutritional supplements, traditional Chinese medicine, and certain non-drug practices, such as meditation.[6,7]

Editorial p 69

The third problem is that the concept of evidence-based medicine, which was once so popular, is highly contested and debated within Western medicine itself.[8] This is because the kind of evidence that is available to clinicians is never more than limited and partial, and that the clinical art always requires different kinds of inputs that set it apart from formal scientific deliberation. As has become widely recognised, clinical judgement draws together a range of skills and theoretical considerations. These include rigorous history-taking and examination, respectful dialogue with patients and relatives to determine the goals of treatment, and assessment of special biological, psychological or cultural conditions, risks, costs and other factors.[9] Evidence from laboratory, epidemiological, clinical research and clinical trial studies cannot solely generate or determine the clinical decisions. These high-level data deal only with populations and probabilities and can, therefore, provide no more than hypotheses to be tested. It is the job of the clinician to convert these data into judgements relating to individual patients. This process of clinical decision making involves forms of judgement and kinds of knowledge that differ qualitatively from those which motivate and direct scientists.[10] Medicine is a complex craft, and a large part of its richness and success depends on its ability to draw on a wide array of practices and forms of knowledge. Despite the undoubted wealth of information that laboratory and population studies provide, from the point of view of the clinician, a great deal of uncertainty remains, at the conceptual and methodological levels. We cannot afford to be overconfident about our own approaches or dismissive of those of others.

This does not mean that there is not a need for a vigorous and forceful debate about systems of medicine and individual practices, and it in no way detracts from the urgent need to protect vulnerable members of the community from those who seek to exploit them. Nor does this mean that we should not continuously re-examine the cultural role that universities play in society and their function is fostering critical learning, creativity and the pursuit of knowledge. These are important questions as they reflect ideas about the degree to which universities should promote or restrict access to different epistemologies and about where, and how, different disciplines and techniques should be taught and learnt. From whatever side one speaks, however, whether from the point of view of medicine or its interlocutors, the institutions of science and health care are too important to be subject to political campaigns seeking to enforce their own preferences regarding what they consider to be true science or how they believe clinical practice should be conducted.

> “What concerns us is a politicised process to apply pressure on governments and educational institutions to act in accordance with the views or convictions of one particular group”

It is important that those who seek to be friends of science do not inadvertently become its enemies. We call on the members of FSM to revise their tactics and instead support open, respectful dialogue in the great spirit and tradition of science itself.

Competing interests: No relevant disclosu es.

Provenance: Not commissioned; externally peer eviewed.

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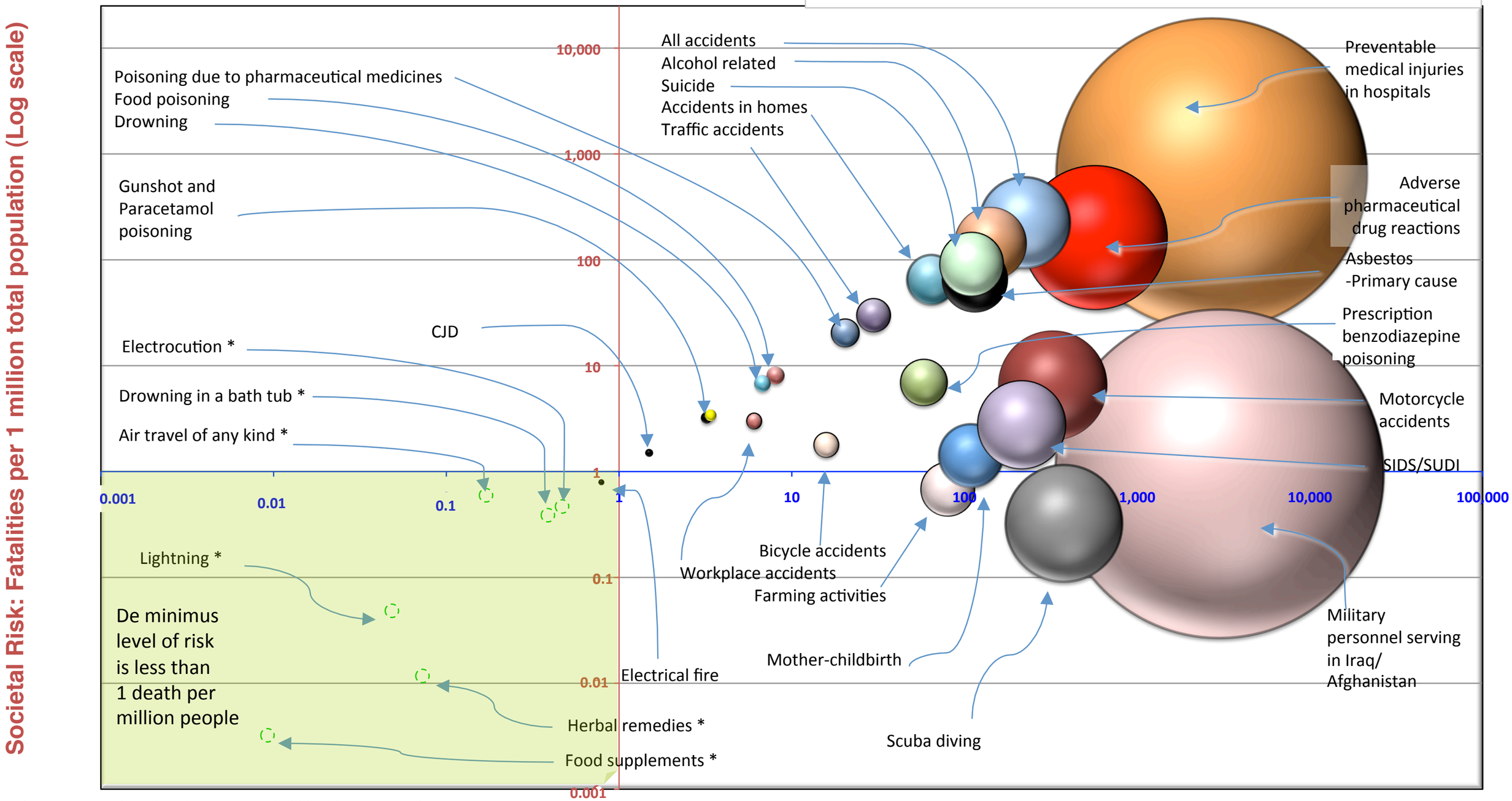
Societal vs Individual Risk of Death in the United Kingdom

Societal risk is represented as the risk of death per million total population.
Individual risk is represented as the risk of death per million exposed to that hazard.
Bubble size represents the relative risk to an individual. By way of example, the bubbles representing deaths due to preventable medical injuries in hospitals and military personnel in Iraq/ Afghanistan are a similar size because the risk of death to a patient in a UK hospital is similar to that for a soldier deployed to a war zone. Medical injury poses a greater risk to society simply because vastly more citizens are exposed to that risk and hence die. **Note: Log scales.**



* Note: Green dotted circles represent bubbles/dots too small to print

v3

Sources: Variety of UK Government and NGO databases, reports, officials and expert advisers.

Commissioned by Alliance for Natural Health International (www.anhinternational.org)
Funding by Neal's Yard Remedies (www.nealsyardremedies.com)

Individual Risk: Fatalities per 1 million people exposed to risk (Log scale)

From: Mary Taylor [redacted]
Sent: Thursday, 6 June 2019 1:11 PM
To: medboardconsultation
Subject: Regulation of integrative GPs / Doctors who provide complementary & unconventional medicine and emerging treatments

To whom this may concern

I am emailing to express my concern that you are looking to limit and control what Integrative Doctors can prescribe and, by doing this, are therefore looking to control and monitor their practice, and to prevent patients from receiving unconventional or emerging treatments.

As someone who regularly sees an Integrative Doctor, with great success and improvements to my illness (which actually makes my visits to doctors far less frequent, and therefore less of a burden on our medical system), and having seen no such success from my regular GP (who saw me for 15 minutes per consultation, and had no idea how to put my symptoms together to decide what tests to order to make a diagnosis), I feel that this is an inexcusable limitation on my rights to seek the appropriate medical attention from a fully qualified GP, whether Integrative or not.

Because of the Integrative GP that I have been seeing for around 8 months now, I have recovered to the point where I feel well again. That's pretty amazing.

To put the limitations you propose in place is not only to deny my rights, but will also deny other patients their rights to appropriate treatment and also to those professional who have worked very hard to gain their accreditation in their respected field.

It would be a sadly retrograde step, and one that would be out of sync with what modern Australian people expect of their medical system. To prevent doctors from accessing and prescribing emerging treatments feels like a retreat to the dark ages. Why would you want to do this? This is actually what happened in the Dark Ages, which is why Medicine took so long to become what it is now. Why would you want to stop progress at this particular point in time? If people want to see GPs who have slightly divergent views from the mainstream, they should be able to. We pay our taxes to support our medical system (amongst many things), and we don't want to be limited to seeing conventional GPs, who are good for things like vaccinations, but not necessarily so good at chronic illness diagnosis and treatment. They simply don't have the time, nor always the interest either.

Yours sincerely

Mary Taylor

From: Suzie taylor [redacted]
Sent: Thursday, 4 April 2019 8:20 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern,
I am alarmed and deeply distressed but the suggested ammenedments towards complimentary medicine.

It seems big pharma is simply winning by taking away peoples freedom to choose heathcare options they prefer.

Some alarming facts to consider:

It is estimated that there are around 650,000 hospital presentations/admissions1 every year due to medication-related problems.
By contrast The Therapeutic Goods Administration has never been able to confirm a single death in Australia that directly resulted from using complementary medicine.

Complementary and alternative medicine (CAM) has become an established part of healthcare for many Australians. CAM is estimated to be used by up to two out of three Australians, and accounts for $3.5 billion in expenditure every year.

Are big pharma threated that such a large chunk of revenue is taken from their coffers???

$4.7 billion complementary medicines industry revenue, having doubled from $2.3 billion in just three years Vitamin & dietary supplement category alone has doubled over the last ten years

Vitamin & dietary supplement category alone has doubled over the last ten years! Why? Because it makes people feel better!! Don't take away peoples rights to choose their healthcare because BIG PHARMA IS GREEDY!!!

"Many countries now recognize the need to develop a cohesive and integrative approach to health care that allows governments, health care practitioners, and, most importantly, those who use health care services, to access T&CM in a safe, respectful, cost-efficient and effective manner." (WHO traditional medicine strategy 2014-2023). Don't make Australia go backwards, lets keep up with the rest of the developed world.

Two significant trends are supporting the growth of the industry in the domestic market: an ageing population and the challenge of increasing chronic disease; and the growing awareness of the importance of preventive health. Increasingly, complementary medicines are being found to contribute to improved health outcomes, through increased effectiveness, safety and cost-effectiveness, and integration with conventional medical care

Australia's Annual Overdose Report 2018 reveals that accidental overdose continues to be a significant cause of death in Australia. The continued growth in overdose deaths is linked to highly potent drugs, many of which are available through prescription, such as pharmaceutical opioids and benzodiazepines. Of the 2,177 drug-related deaths in 2016, the majority (1,704) were accidental. Fifteen years ago in 2002, the number of accidental drug-related deaths was 903.
WHY ARENT BIG PHARMA BEING SCRUTINISED FOR THIS, AS HEAVILY AS COMPLIMENTARY PRACTITIONERS WHERE THERE HAVE BEEN NO DEATHS FROM THE THERAPIES THEY PRESCRIBE?

I look forward to your reply

Have a great day
Best Regards

Suzie Taylor

Dear Medical Board of Australia,

I have read your consultation paper on regulation of the subject topic.

It is clear that Option 2 should be adopted.

I do have considerable concerns regarding adverse events from complementary and unconventional medicine and emerging treatments (and indeed conventional).

They are vastly under-reported.

I would suggest that rather than being subparagraph 7.5 that it be expanded to its own paragraph and considerably more forceful language and greater indicative examples be given. The need for reporting adverse events cannot be overestimated in my opinion.

Thank you for your work.

Regards,
Warren Taylor

From: Kumudu Thirimavithana [redacted]
Sent: Sunday, 30 June 2019 9:28 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

To The Medical Board of Australia
I support Option 1 - Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

I have personally benefitted from integrative medicine. I have also seen my family and friends benefitted from integrative medicine. I believe the conventional medicine is unable to effectively address many chronic conditions without long term prescribed medication. This approach is making patients having to take medication for a very long time (rest of their lives in certain cases) and believing that there is no other solution. This approach is fundamentally flawed.

Please do not introduce any guidelines on integrative and emerging therapies which will limit my choices.

I **do** provide my consent to publication of my submission.
I **do not** provide consent to forwarding my submission to Health Minister or any other elected member of the state or federal parliment.

Yours sincerely
Kumudu Thirimavithana

To: Medical Board of Australia

medboardconsultation@ahpra.gov.au

Submission in regard to:

Consultation on complementary and unconventional and emerging treatments

Submitted by: Richard Thomas

28 June 2019

I choose Option 1 - Do not introduce new regulations, especially at this time.
Reasons are based upon the options presented and proposed by the Medical Board.

oooOooo

"The Board is proposing the following definition:
A: Complementary and unconventional medicine and emerging treatments include any assessment, diagnostic technique or procedure, diagnosis, practice 1, medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.

[1] ***Practice*** *means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a health practitioner in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effective delivery of services in the profession.*

B: Options
The Board has identified two options in developing this proposal.
Option 1 - Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.
Option 2 - Strengthen current guidance for medical practitioners who provide complementary and unconventional medicine and emerging treatments through practice-specific guidelines that clearly articulate the Board's expectations of all medical practitioners and supplement the Board's Good medical practice: A code of conduct for doctors in Australia.
C: Preferred option
The Board prefers Option 2."

oooOooo

A: The definition title is vague, ie, not actually a definition. [
The MBA needs to be aware of the deficiencies in the conventions of conventional medicine
The somewhat myopic view regarding options to (current) healthcare options available by modalities outside the confines of the conventional medical doctrine are all effectively excluded by the proposal.
[Shades of the suggestion of the MBA being "The Thought Police' [Guardian xxxxx
The MBA seeks to deny the Australian community health options other than embraced by the theories and protocols of current beliefs.
Vague terminology/'definition' such as:
"treatment that is not usually considered to be part of conventional medicine", and
"whether used in addition to ,or instead of, conventional medicine."

B: Options
Under the current circumstances **Option 1** is the only viable option especially in view of activities in other areas, eg., Chief Medical Officer's review of Complementary and Alternative Medicines, due for completion by mid 2020.
In the meantime it would give the Medical Board the opportunity to develop a better understanding of what Complementary, Alternative and Integrative Medicines actually involve and the benefits to the Australian community, especially areas where conventional medicine options are less than safe/effective compared with other available options supported by reliable evidence.
Option 2 is simply not viable, especially
- at this point in time,and,
- as the already existing *Board's Good Medical Practice:A Code of Conduct for Doctors in Australia* is already in place

In the meantime it would give the Medical Board the opportunity to develop a better understanding of what Complementary, Alternative and Integrative Medicines actually involve and the benefits to the Australian community, especially areas where conventional medicine options are less than safe/effective compared with other available options which are supported by reliable evidence.

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Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

The Board is inviting feedback on the issues and options outlined in the discussion paper.

1. Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'?

   No. Definitely not. The selected term [certainly not a definition] is very vague and has important implications.

   If not, what term should be used and how should it be defined?

   The term "Complementary and Alternative Modalities" is much more definitive and clearer. It encompasses all options other than conventional medicine.

2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments - 'any assessment, diagnostic technique or procedure, diagnosis, practice medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.'

   If not, how should it be defined?

   The proposed definition is not a definition - it is a vague and limiting set of constraints. The limiting conditions listed in concept of practice creates contradiction with the aims of the MBA.

3. Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'?

   Definitely not. The nature and issues were limited/restricted by the institutional mindset of the MBA and not based upon a genuine desire to ensure the highest quality healthcare options for the Australian community.

4. Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners that the Board has not identified?

   Numerous. But, subject to a genuine desire within the MBA to address these.

5. Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'?

   These are already addressed in the existing MBA guide. But, issues regarding education, training and support need to be addressed. The issue of 'rogue' medical practitioners is, likewise, also addressed.

6. Is there other evidence and data available that could help inform the Board's proposals?

   Yes. There is a wealth of information and evidence which has been ignored/excluded/rejected by allied reviewers of CAM within Australia. This requires a genuine, objective and scientific frame of mind to pursue. The current dichotomy of "discuss the use of CAM with your medical practitioner" combined with the uninformed resistance to education, training, research and participation is a problem.

Options

7. Is the current regulation (i.e. the Board's *Good medical practice*) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?

Yes.

8. Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?

No. Definitely not. [The title of the consultation says "regulation <u>of</u> medical practitioners", then this says "regulation <u>for</u> medical practitioners"] Q: Was the title a 'freudian slip'?

9. The Board seeks feedback on the draft guidelines (option two) – are there elements of the draft guidelines that should be amended? Is there additional guidance that should be included?

Option two is 'fatally flawed', to the extent it cannot be considered in its presented form.

10. Are there other options for addressing the concerns that the Board has not identified?

Numerous. But it would involve changes/upgrading the institutional mindset to include factors outside the realm of 'echo chamber' thinking.

11. Which option do you think best addresses the issues identified in relation to medical practitioners who provide complementary and unconventional medicine and emerging treatments?

5.1. Option one: Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

5.2. Option 2: Strengthen current guidance for medical practitioners who provide complementary and unconventional medicine and emerging treatments through practice-specific guidelines that clearly articulate the Board's expectations of all medical practitioners and supplement the Board's *Good medical practice: A code of conduct for doctors in Australia*.

5.3. Other: please specify.

Option 1 is the only viable option to be considered at this time.
Option Other could be entertained later when all the flaws, deficiencies and vagueness of Option 2 are addressed and a clear need is found.

From: brenton [redacted]
Sent: Saturday, 20 April 2019 11:44 AM
To: medboardconsultation
Subject: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

To whom it may concern
Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.
Specifically, it is alarming that once again Lyme Disease (or Lyme-Like and associated tick borne illnesses) has been called out as an area of concern. It is disappointing to see that Australia is so far behind the latest peer reviewed research in this area, and even more shocking that the Medical Board intend on creating a set of guidelines which will more than likely restrict our highly capable doctors from practising good health care, which is not entirely based on outdated options that come from large pharmaceutical and insurance companies.
Imposing an increase in restrictions through changes to the guidelines will almost certainly stifle innovation and advancement of medical treatment options available in this country, and not just pertaining to Lyme Disease, but to other chronic and disabling illnesses. Australia's medical system will slip even further down the rankings than it already is. Perhaps we should look to progressive countries such as Switzerland who are doing the complete opposite and are encouraging the use of complementary medicines?
I have family and friends who use Complementary, Unconventional and Emerging Medicine and I highly value its availability and I am very happy with its practice. Treating doctors already provide discussion about options for treatment and their relative merits and potential problems. I value free choice in making decisions regarding my own personal medical treatment.
The suggestion of strengthened guidelines is far too controlled, an attack on my human right to seek any treatment I choose to use with my chosen health professional. Whether you agree or not with the diagnoses, the treatment plans, it is not the Medical Board's decision to hold my future at jeopardy because of its own antiquated ideology.
As such, my preferred choice of the proposed outcomes is to retain the status quo, otherwise fellow sufferers will only have the option of travelling overseas, where they are at even greater risk of complications. Australia is not a third world country, and my expectation is that we as Australians should be able to attain the treatment of our choice, here at home.

Your sincerely
Brenton Thompson
20/04/2019

From: Danielle Thompson [redacted]
Sent: Wednesday, 10 April 2019 11:27 PM
To: medboardconsultation
Subject: RE: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

To whom it may concern

Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.

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Your sincerely

Danielle Thompson

10th April 2019

From: [redacted]
Sent: Friday, 28 June 2019 4:36 PM
To: medboardconsultation
Subject: Review of doctor's ability to use complementary and unconventional medicine and emerging treatments.

As there is no cure or effective standardized treatment from a traditional medical approach for my condition, I feel that it is essential that my doctor has the ability to utilize complementary and unconventional medicine and emerging treatments, in treating and improving my overall health.

Thanks

HK Thompson

From: Jen Thompson [redacted]
Sent: Thursday, 11 April 2019 7:28 PM
To: medboardconsultation
Subject: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

Executive Officer
Medical - AHPRA
GPO Box 9958
Melbourne VIC 3001

RE: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENT

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Your sincerely
Jennifer Thompson
11/04/2019

From: Jodie Thompson [redacted]
Sent: Tuesday, 16 April 2019 7:02 PM
To: medboardconsultation

Executive Officer
Medical - AHPRA
GPO Box 9958
Melbourne VIC 3001
medboardconsultation@ahpra.gov.au
RE: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

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Your sincerely
Jodie Thompson
16th April 2019

From: Lisa Thornton [redacted]
Sent: Sunday, 30 June 2019 7:03 PM
To: medboardconsultation
Subject: Medical doctor having the right to choose

I want the right to choose my doctors
I want to be involved in my own and my family's care and this requires time in consultations an additional medical training that I found in my integrative medicine doctor.
I want more from my doctor. More time. More understanding of causes of illness. More power to understand the ways in which I can improve my health to reduce my need for drugs, surgery and medical appointments. My Integrative Medicine doctor provides these for me in a way that 10 minute consultations with doctors cannot.Ive concerns about the proposed regulations because:
There is no demonstrated need to regulate Complementary Medicine or Integrative Medicine. These are safe practices that need no further regulation.
The only concern of the Medical Board of Australia in this process is, and should be, safety. The Chair has said this publicly. Questions about how effective Complementary Medicine and Integrative Medicine is should be a decision left to me.
The Medical Board of Australia includes members of the Friends of Science in Medicine, a political lobby group opposing Complementary Medicine and Integrative Medicine. This is a clear conflict of interest. The Medical Board of Australia should cancel the current consultation, and go back to the start with all current and past members of the Friends of Science in Medicine lobby group excluded from Board participation.
There has been no transparency in consultation process. Freedom of Information requests as to how these proposals originated have been denied or redacted. The Medical Board of Australia has acted in secrecy and a failure to disclose the details of why the new regulations.

From: [redacted]
Sent: Saturday, 6 April 2019 1:47 PM
To: medboardconsultation
Subject: Health Care of My Choice

Medical Board Submission

Regarding the public consultation on clearer
regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

As an Australian
citizen/resident I feel it's important that I have the freedom of choice in the type of medical care that I use to address my chronic health issues.

I have been suffering from :

Conventional medical doctors
have not been able to successfully treat my condition(s) and bring me to a satisfactory level of health.

Pharmaceuticals and the use of
conventional methods simply did not work (and in some instances also delivered unwanted side-effects in my case) and, seemed to waste Medicare funds and resources.

It was only when I saw an
integrative medical doctor who included lifestyle change, diet and supplements of vitamins and minerals to address my problems that my condition began to improve.

If I cannot see an integrative
doctor, or the Doctor is restricted in what he or she is able to prescribe for me, I feel that my health will deteriorate and have a continuing impact on my family, my work, and my wellbeing.

Additional notes:

Concerned,

Name:Rhonda Thrush
_____

email –[redacted]
_____

Date:
_0__6____/_04_____/__2019_____

From: [redacted]
Sent: Thursday, 27 June 2019 10:07 AM
To: medboardconsultation
Subject: SUBMISSION to "Discussion paper on Consultation on complementary and unconventional medicine.

AHPRA
Canberra
ACT
medboardconsultation@ahpra.gov.au
26/6/2019

Dear Sir/Madam,
I am contacting you in regards to the discussion paper 'Consultation on complementary and unconventional medicine and emerging treatments'

How can this be a considered a “discussion paper” when NO consultation with the Integrative Medicine or complementary medicine community before the document's release. NO media release to the broader community to gain their opinion on the potential infringement on their personal right to choice.

I believe that Integrative medicine HAS sufficient evidence based treatments that it should not be grouped with the terms 'unconventional medicine' and 'emerging treatments'. As many treatments have a long history of efficacy and safety.

The TERM “complementary medicines” would also include “Traditional medicines”, which is absurd. The right of patients to determine their own medical care is under threat! I a patient wishes to use a “Traditional medicine” with little proven efficacy but is of low risk *they should have the right to do so*!

This process is simply pandering to the pharmaceutical company’s push into takeover of natural medicine ingredients of which there is many examples.
The public has the right to know the pharmaceutical company’s agenda of securing natural ingredients under patient which would then significantly reduce access and then increase the cost to the public.

I believe *the paper should be dumped* and that a REAL discussion take place that includes ALL stake holders including the public that has the right to make personal choices with their health!

I look forward to your response.

Sincerely
Will Tidswell
Phone [redacted]
Email [redacted]

From: Sandra Tindall [redacted]
Sent: Friday, 10 May 2019 6:06 PM
To: medboardconsultation
Subject: Sandy Tindall

To whom it may concern..
Under no circumstances do I believe you have the right to take my freedom away to choose what is best for me regarding my health!!!
I am advocating Integrative medicine for myself and family... our country prides itself on democracy!!!!
And if that is truth you cannot take this right away it's inconceivable you would even consider it !!!!
I have the utmost respect and gratitude for my family Dr who practices Integrated medicine she searches for the cause and heals rather than bandaids and if you believe that is the wrong way to practice medicine then it make me ask what is the real motivation behind your cause for these changes , and if you believe we will do nothing you are wrong !!!!
I am 1 of many and we will stand together I promise you that !!!! we are not sheep to be herded and controlled ...
Regards Sandra Tindall

From: [redacted]
Sent: Friday, 15 March 2019 11:39 PM
To: medboardconsultation
Subject: Consultation on Complementary Medicine

I have read with great concern that the MBA is carrying out a Consultation on Complementary and Unconventional Medicine and Emerging Treatments.
I am a great supporter of food supplements and herbal medicines. I am a very healthy person and am sure this is the result of a healthy diet, plenty of exercise and good food supplements.
I strongly believe in our citizen right to freedom of choice and am sure it is safer to have a good diet complemented by high quality food supplements, that have never killed anyone, than to take prescription drugs that have been proven to have worse side effects than the illness they are supposed to be curing and even kill.
I strongly urge you to consider carefully your decisions on the above consultation.
Anne Tola

From: Lisa [redacted]
Sent: Thursday, 27 June 2019 8:23 AM
To: medboardconsultation
Subject: Fwd: Consultation on complementary and unconventional medicine and emerging treatments

>
> I choose Option 1: “no new regulations are required for doctors
> practising in the areas of complementary medicine and integrative
> medicine.”
> I have chosen to see Integrative Medicine doctors because:
> I want to be involved in my own and my family’s care and this requires
> time in consultations an additional medical training that I found in
> my integrative medicine doctor.
> Conventional medicine provided no answers about why I was sick and I
> needed medical care with a wider range of diagnostic and treatment
> options.
> I have been harmed by conventional medical treatment, and needed to
> find other options.
> I prefer non-drug approaches for managing my family’s and my own
> health or illnesses.
> I am happy with my GP for simple treatments within brief
> consultations, but I want to go further with prevention and a deeper
> understanding of what I can do for myself and my family. My
> integrative medicine doctor provides me the time and knowledge to do
> that.
> I want more from my doctor. More time. More understanding of causes of
> illness. More power to understand the ways in which I can improve my
> health to reduce my need for drugs, surgery and medical appointments.
> My Integrative Medicine doctor provides these for me in a way that 10
> minute consultations with doctors cannot.
> I have concerns about the proposed regulations because:
> There is no demonstrated need to regulate Complementary Medicine or
> Integrative Medicine. These are safe practices that need no further
> regulation.
> The only concern of the Medical Board of Australia in this process is,
> and should be, safety. The Chair has said this publicly. Questions
> about how effective Complementary Medicine and Integrative Medicine is
> should be a decision left to me.
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> Science in Medicine, a political lobby group opposing Complementary
> Medicine and Integrative Medicine. This is a clear conflict of
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> Information requests as to how these proposals originated have been
> denied or redacted. The Medical Board of Australia has acted in
> secrecy and a failure to disclose the details of why the new
> regulations.

Lisa Tong

From: Dave Toohey [redacted]
Sent: Monday, 1 April 2019 12:16 PM
To: medboardconsultation
Subject: Proposal to change regulations for complementary and unconventional and emerging medicine

To the Executive Officer,

My name is David Toohey, I am [redacted] years of age and reside in [redacted].

I am extremely concerned with the medical boards proposal to create a new set of regulations governing the practice of complementary and unconventional and emerging medicine. Proposing to apply a new set of guidelines to one group of medical practitioners and not to another appears highly discriminatory.
Where is the evidence that complementary and unconventional medicine have more complaints and more severe outcomes than other forms of medical practice?
Why can the current guidelines for good medical practice not continue for all forms of medical practice? Why can the status quo not remain? This is my preferred outcome.

I have used unconventional and complementary and emerging medicines for over a decade and am more than happy with its practice. My doctor provides treatment options, highlighting possible problems and merits in these medicines. Above all, having a free choice to choose my preferred medical treatment is of the utmost importance to me.

Retaining the status quo is my preferred outcome. If the Medical Board does decide to opt for greater regulation, the current proposal must be modified to ensure that it applies to ALL medical practitioners who would all be under the same guidelines to provide exhaustive expositions on all treatment options and research. To propose any other option would be highly discriminatory and moreover take away my individual right to choose my own treatment options.

I urge that the Board accepts that Integrative medicine, utilising complementary or unconventional or emerging medicine as well as conventional medicine, be recognised as a speciality, allowing Medicare rebates to increase in order to help cover the cost associated with fulfilling the new regulations.

Please reconsider this discriminatory proposal.

Regards

David Toohey

From: [redacted]
Sent: Monday, 1 April 2019 12:14 PM
To: medboardconsultation
Subject: Australian Medical Board proposal re. complementary and unconventional and emerging Medicine

To the Executive Officer,

My name is Kylie Toohey, I am [redacted] years of age and reside in [redacted].

I am extremely concerned with the medical boards proposal to create a new set of regulations governing the practice of complementary and unconventional and emerging medicine. Proposing to apply a new set of guidelines to one group of medical practitioners and not to another appears highly discriminatory.
Where is the evidence that complementary and unconventional medicine have more complaints and more severe outcomes than other forms of medical practice?
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Please reconsider this discriminatory proposal.

Regards
Kylie Toohey

From: Melissa Toovey [redacted]
Sent: Thursday, 4 April 2019 9:49 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Medical Board of Australia,

I am writing to show my strong support for option one - do not introduce new regulations, in your latest proposal regarding conventional and emerging treatments.

I have personally experienced the benefit of complementary medicines, which was hardly 'unconventional' practice. Where 20th-century medicine and specialists failed me, an integrative doctor treated my total health. We cannot deter these doctors as we risk reducing patient choice - and I wonder myself if I had not found this doctor how different my life would be today.

In closing, please do not change the current regulations. Give doctors and patients a choice to embrace new practice and don't limit our options.

Thanks,
Melissa

From: Wendy [redacted]
Sent: Thursday, 13 June 2019 9:00 PM
To: medboardconsultation
Subject: Public consultation on clearer regulation of medical practitioners

I agree with

*Option 1 - Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

To curtail the ability of practitioners from the above could inhibit effective treatment for those who need or desire alternatives. This could also see them seek help from overseas or unqualified practitioners. The alternative option attacks the skill, integrity and professionalism of medical practitioners providing care.

regards
Wendy Townrow

--
[redacted]

From: Debbie Tsagatos [redacted]
Sent: Friday, 7 June 2019 6:04 PM
To: medboardconsultation
Subject: Integrative Medicine review

Hi,

I am a consumer and strong supporter of Integrative Health Medicine.

As part of your review of the new guidelines for 'complementary and unconventional medicine and emerging treatments', I am concerned about the following issues:

- The grouping of integrative medicine with 'unconventional medicine' and 'emerging treatments' may create the impression of being "fringe" rather than evidence-based
- That many of the terms used in the rationale such as 'unconventional medicine', 'inappropriate use' and 'emerging treatments' leads to ambiguity and uncertainty
- That the term 'complementary medicine' also includes access to traditional medicines
- No evidence produced in the discussion paper quantifies risk in practicing complementary or integrative medicine vs 'conventional' medicine
- That there was NO consultation with the Integrative Medicine or complementary medicine community before the document's release
- That the current Good Medical Practice: A Code of Conduct for Doctors in Australia already adequately regulates doctors' practise and protects patient safety. There is no need or justification for a two-tiered approach
- That the right of patients to determine their own medical care is under threat
- That the lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion which results in troublesome complaints

Integrative Medicine looks at the client as a whole, recognising that what happens in one part of the body affects other parts. It is important that consumers continue to be able to access this service as a part of a functionally complete medical system, not as a separate side.

Regards,
Debbie Tsagatos
[redacted]

Public Consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

To: The Medical Board of Australia
From: Peter Twigg
Telephone: [redacted]
E-mail: [redacted]
Website: N/a
Date: 28th June 2019

CC
Members of Parliament

Consultation
I, Edward Peter Twigg, Economist and Public Choice Theorist, appreciate the opportunity to participate in providing comments on the Medical Board of Australia's recent public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

I have referred this matter to other parties in government for further investigation.

Submission

The Medical Board of Australia has released a public consultation paper seeking feedback on options for clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

The role of the MBA is to:

- register medical practitioners and medical students
- develops standards, codes and guidelines for the medical profession
- investigates notifications and complaints about medical practitioners
- where necessary, conducts panel hearings and refers serious matters to Tribunal hearings
- assesses international medical graduates who wish to practise in Australia, and
- approves accreditation standards and accredited courses of study.

Poor Execution
The MBA consultation paper was introduced, attempting to push through the outcome before the public could respond. This brought an outcry from the profession and public forcing the MBA to extend the consultation until 30th June 2019 from 12h April 2019.

The consultation limits the scope of feedback allowable thereby skewing the response. For example, the submission template skews the response immediately by referring to unconventional medicine. It conflates emerging treatments with unconventional medicine and complementary medicine. The required terminology has long been in place and is recognised internationally.

The MBA undertook this consultation without any initial consultation with associations or all medical profession stakeholders. To meet protocol the MBA then engaged this public consultation in a rushed manner.

The proposed outcomes showed a biased assumption about the possible outcomes. This entire process has raised questions about the MBA and its impartiality. It raises questions about the lack of oversight and inherent conflict of interest displayed by the MBA. It also

demonstrates the MBA's poor insight into the healthcare industry and the execution of this consultation.

Unintended Consequences
The proposal options stated by the MBA would result in changes to the way IM doctors to conduct their medical practice implementing complementary and alternative medicine. An onus would also be placed on all doctors **not** using complementary and alternative medicine to quiz all patients using complementary and alternative medicine, to advise them of their experimental and unproven nature, and report if necessary. It places an impossible compliance burden on any doctor using complementary and alternative medicine to present the evidence of benefit for each prescription, treatment and referral, and that each doctor provides comparisons of the benefit and risks with conventional practice.

The time and burden on a medical practitioner for the paperwork and discussion would be costly and would detract from patient care and increase the costs to patients massively in order to cover the paperwork, admin, research and more.

Professional Dispute
The heart of the matter is a professional disagreement between two groups within the medical profession who have different ideas about the treatment of chronic illnesses. This is not the remit of the MBA.

The two groups involve the Friends of Science in Medicine (FSM) and Integrative Medicine doctors (IM) represented by their association AIMA.

FSM sponsors a narrowly defined scientific view of how medicine should be practiced that does not account for the national interest, patients or industry participants. The FSM have published their views in papers published on their website where they openly attack their IM medical colleagues and the innovative, cost effective approaches being undertaken by IM doctors.

As defined by the U.S. National Center for Complementary and Alternative Medicine at the National Institutes of Health, integrative medicine "combines mainstream medical therapies and CAM therapies for which there is high-quality scientific evidence of safety and effectiveness." In other words, integrative medicine "cherry picks" the very best, scientifically validated therapies from both conventional and complementary and alternative medicine systems.

FSM is the group responsible for taking naturopaths, homeopaths and other complimentary health practitioners out of private health insurance cover**.** FSM successfully advocated the removal of private health insurance taxpayer-funded rebates from "natural" therapies that they considered lacked evidence of efficacy. Despite empirical evidence lasting hundreds of years in the case of homeopathy, thousands in the case of acupuncture and herbalism, not to mention the body of scientific research on nutrition and nutritional supplements, the body of evidence provided by empirical observation does not meet the "scientific" views of the FSM.

For example, the approach taken by FSM in the interest of 'scientific protocols' takes a 'we know better than you' disciplinary approach to conventional medicine doctors when it states:

'…. a GP might practice in the same clinic with a homeopath and a chiropractor or other pseudoscience-based practitioner. Frequently the doctors involved claim that they are merely responding to consumer demand.

One can legitimately question whether GPs who ally themselves with practitioners of pseudoscience in their group practice betray their Hippocratic duty of care to their patients and whether, in so doing, they fail in their commitment to offer the evidence-based and scientifically-based Medicine that society expects.'

As the new President of the FSM Monash University Associate Professor Ken Harvey AM comments on his appointment:

> 'We critique unproven and exploitative services offered by medical practitioners, such as the infusion of intravenous vitamins and chelation therapy.'

The field of nutritional, lifestyle and environmental medicine today stems from strong and voluminous scientific evidence. Nutrition and lifestyle medicine are accepted as mainstream by scientists, healthcare practitioners and patients alike. It seems the FSM has a comprehensive understanding of **all** approaches to medicine and judges the efficacy of each therapy according to their narrow scientific view of how medicine should be practiced.

By contrast, 'Integrative Medicine' is increasingly used to describe "the practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, healthcare professionals and disciplines to achieve optimal health and healing".

Unaccountability

MBA is an unaccountable agency that does not have any parliamentary or departmental scrutiny. It has the scope and license to implement standards, codes and guidelines that shape lives and industries. The MBA has undertaken this consultation with a view to inserting more red tape on the way IM doctors practice. This is a slippery slope that does not satisfy patient or national interest. It appears the MBA has become a rogue government agency, exceeding its mandate.

According to the MBA, concerns have been raised by stakeholders about this area of practice suggesting that additional guidance for medical practitioners is needed to support safe practice and ensure safeguards for patients.

Conflict of Interest

It is disturbing then to observe two prominent members of the MBA are also active members of FSM. The agenda proposed by FSM is identical to the agenda being promoted by the MBA. Clearly there is a conflict of interest by Dr Anne Tonkin, Chair, Medical Board of Australia and Associate Professor Stephen Adelstein, Practitioner Member, NSW in delivering impartial, national interest based, patient-centric healthcare policies.

Scientific rigour is especially important in an age where unsubstantiated claims are rampant and scientific consensus is 'imbalanced' by the views of extremists on both sides of the debate. It seems FSM and its ally, the Skeptics is not immune to criticism for their 'scientifism' approach to healthcare.

The empirical and scientifically validated evidence supporting complementary and alternative medicine therapies have been around for decades and centuries. New emerging therapies (e.g. stem cell therapy, robotic surgery) are starting to impact the way healthcare is administered creating a whole new world of healthcare with standards, ethics and protocols that need to be developed. It seems the FSM in its attack on IM doctors, simply refuses to accept the evidence at hand nor remain open to new and emerging therapies.

Qui Bono?
Who benefits most from IM doctors being unable to provide complementary, alternative and emerging medicine treatments in healthcare? Clearly conventional doctors and the pharmaceutical industry stand to benefit the most as patients are corralled into using pharmaceutical solutions to their healthcare problems. Government also benefits, as administratively it is easier to provide a one stop shop approach to Australian healthcare.

Questions Unanswered
Is it that vested interest of Big Pharma approaches to conventional medicine are being threatened? Are conventional medicine practitioners losing income because a dubious public look for less invasive, less expensive, less pharma, more holistic answers to their health problems?

Perhaps the FSM should be more focussed on reducing Iatrogenic Illness through more rigorous research into existing pharmaceutical and medical devices? As The Pharmaceutical Society of Australia 2019 Report, Medicine Safety: Take Care demonstrates: 250,000 hospital admissions annually are a result of medication-related problems with an annual cost $1.4 billion. 400,000 additional presentations to emergency departments are likely to be due to medication-related problems

Employment
The supplements industry employs thousands of people and is an Australian billion-dollar industry. It has an international reputation for producing high quality, affordable products. The initiatives being sponsored by FSM and being furthered by the MBA impacts the competitiveness of the supplements industry and certainly impacts employment. Furthermore, Australian healthcare patients simply engage in medical tourism when they travel overseas to get the choice of product and healthcare they want. Often at more affordable prices.

Healthcare Costs, Competition & Choice
At a time when government is trying to keep healthcare costs down, it's incumbent on government to attract as much competition and diversity in healthcare as it can muster. Competition has always been in the best interests of the consumer and third-party payers (government, private health insurers).

Government systematically and typically tries to create one size fits all solutions as it is easier to administer. Government role should not be to create one stop shops simply because of ease of administration, but to provide scope for a range of solutions meeting Australian healthcare needs.

The MBA is adjudicating issues where it has no remit and remains totally unaware of the short and long-term ramifications of MBA policy and standards formulation in this matter. The effect is to cause loss of choice for people seeking healthcare treatment. It drives up costs. Often sick people turn to IM when they have exhausted orthodox medicine approaches to their health problems found in chronic disease. People recognize long term pharmaceutical treatments may check medical conditions but doesn't necessarily restore full health.

By implementing these new guidelines, evidence-based IM doctors will be caught in the FSM sponsored MBA witch hunt. Better the MBA raise education standards for all healthcare practitioners and clearly define the operating boundaries of each profession. Similarly, many

Australians see IM and CAM therapies as a better first step due to the risks associated with surgery, pharmaceutical interventions and other processes.

Public Choice Theory Perspective & Conclusion

Public Choice Theory examination of this matter suggests FSM has used the MBA, an unaccountable government agency to squeeze complementary and alternative medicine professions out. FSM is now attacking IM doctors directly and indirectly. This is rent-seeking and how the elite garner favour, privilege, position and reward. Rent-seeking is the effort to capture special monopoly privileges, usually by manipulating government departments and regulations in their favour.

Is this why doctors in the FSM camp feel so threatened? It's clearly not about evidence-based medicine, it's more about the money and perks of privileged position. MBA is an unwitting pawn in the game. IM and complementary and alternative medicine therapies have helped to establish a broad and robust market for healthcare in Australia. Hopefully this has helped to cap spiralling healthcare costs in Australia. Having a rent-seeking bunch of privileged doctors squeezing out fellow doctors because of self-interest does not benefit patients or the healthcare industry at large.

The MBA must step back from the unintended consequences of these proposed initiatives in the interests of maintaining a viable, cost effective, competitive healthcare system.

"In 300 years, doctors will look back at this time and consider how barbaric medicine was, just as doctors now look at medical practice 300 years ago and consider practices, then, to be barbaric."

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Public Consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

References

Public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments: (Internet ref 23/06/2019): https://www.medicalboard.gov.au/documents/default.aspx

Role of Medical Board of Australia: (Internet ref 23/06/2019): https://www.medicalboard.gov.au/About.aspx

Definition U.S. National Center for Complementary and Alternative Medicine: (Internet ref 23/06/2019): https://nccih.nih.gov/about

Friends of Science in Medicine Position Document on Complementary Alternative Medicines: (Internet ref 23/06/2019): https://www.scienceinmedicine.org.au/what-do-we-stand-for/position-document/#PDMP12

What is Integrative Medicine: (Internet ref 23/06/2019): https://www.drweil.com/health-wellness/balanced-living/meet-dr-weil/what-is-integrative-medicine/

FSM president appointment: Medical Journal of Australia: (Internet ref 23/06/2019): https://insightplus.mja.com.au/2019/5/research-news-in-brief-85/

Conventional Doctors Practising with COMPLEMENTARY AND ALTERNATIVE MEDICINE professionals: (Internet ref 23/06/2019): https://www.scienceinmedicine.org.au/what-do-we-stand-for/position-document/#PDMP09

Choice of Doctors: (Internet ref 23/06/2019): https://www.ourchoice.org.au/

Scientifism: (Internet ref 23/06/2019): https://septicskeptics.com/author/septicskeptics/

The Pharmaceutical Society of Australia 2019 Report, Medicine Safety: (Internet ref 23/06/2019): https://www.psa.org.au/wp-content/uploads/2019/01/PSA-Medicine-Safety-Report.pdf

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From: Graeme Tychsen [redacted]
Sent: Sunday, 30 June 2019 12:16 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments'.

Dear MBA

Joining 'complementary medicine, with unconventional medicine and emerging therapies', into a single definition, is misleading; not soundly based.

Yours sincerely

Graeme Tychsen
[redacted]

[redacted]

From: Kim van Niekerk [redacted]
Sent: Thursday, 27 June 2019 9:07 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

I choose Option 1...

I am very concerned by this proposed regulation because people should have access to as many forms of medicine as possible - Allopathic/conventional, complementary and integrative. People are different and what may work for one may not work for another. Also I like to be able to have a choice. If one form of medicine doesn't work then I have an option to try something else. Also if in one instance Complementary might be the best option for me in another Allopathic might be the best or Integrative.

Stop trying to regulate our choices we are adults and are capable of making these choices for ourselves. If a specific practitioner has been found to be doing things that endanger the public then that practitioner should be punished not the entire medical discipline. There are bad practitioners in all three types of medicines so this is not the way to go about it.

I also have concerns about there being a conflict of interest with some board members also being members of the Friends of Science medicine lobby group and any MBA members who have this or any other conflict of interest should not be involved in this decision.

Kind regards Kim

From: Emeshe Varga [redacted]
Sent: Monday, 10 June 2019 4:37 PM
To: medboardconsultation
Subject: Integrative Doctor

To whom this may concern,

I am emailing to express my concern that you are looking to limit and control what Integrative Doctors can prescribe and by doing this, are therefore looking to control their practice. As someone who regularly sees and Integrative Doctor, with great success and improvements to my illnesses, having seen no such success from my regular GP, I feel that this is an abhorrent limitation on my rights to seek the appropriate medical attention. To put these limitations in place is to not only deny my individual rights, but will also deny thousands of other patients their rights to appropriate treatment and also to those professionals who have worked very hard to gain their accreditations in their respected field.

Kind regards,
--
Emeshe Varga
P: [redacted]
E [redacted]

From: Christine Vasilevski [redacted]
Sent: Thursday, 27 June 2019 10:47 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

To whom it may concern,

It is with disgust that I write this letter after reading the proposed regulation of medical practitioners. This regulation is NOT for the benefit of patients and our country- it is being pushed forward out of arrogance. On behalf of Australia, I am embarrassed that the Medical Board of Australia is trying to force our doctors to not use complementary medicine when the rest of the world is advancing in this direction. It truly does show how narrow minded you are.

Complementary medicine has been researched and proven to be beneficial. The fact that you choose to ignore this is arrogant, egotistic and just shows what a bully you are. For an industry that is "all about the research and science", use your skills in research and science to educate yourself in complementary medicine as you are obviously intentionally ignoring all of the evidence.

I have seen in the past a doctor who incorporated researched lifestyle and nutritional advice and he was the ONLY person who helped me. Every other doctor had no idea what was affecting me and why I was so sick. By removing his right to practise this way means you are just letting this country get sicker and stay sick.

It is so sad to think that you do not value a persons right to be well and healthy. You only want them to stay sick- is that where the money is??? The rest of the world will be shaking their head at Australia.

After the removal of natural medicine from private health funds, it is now very obvious that there is an attack on Natural Medicine. You should be ashamed of yourself.

Christine Vasilevski

From: [redacted]
Sent: Monday, 15 April 2019 2:25 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

To Whom it May Concern

You have no right to dictate whether or not people can choose to use Natural medicine or not. However, as you believe you do please note that I am lodging my formal objection.

If this is to be up for debate note that I support Option 1. Leave people and decent conventional practitioners to choose what will help their patients.

Natural medicine does not take away the need to utilise a conventional doctor when required. It should be seen by those who are not afraid as a compliment and preventative practice. Any decent practitioner who is truely wishing for the best health outcome for their patients would use all available resources. Especially when it alleviates the already overburden public health system. It is also important to note that any conventional practitioner would be up with the latest science based results for Natural medicine.

I fully object to this boards proposed change in the definition of Complementary and unconventional medicines. It was not so long ago that conventional medicine was exactly that of Natural medicines. Most of conventional medicines are based on the very foundation of Natural medicines. However, it is just that plants cannot be patented. This board has no right to disadvantage many, many Australian citizens who want to be able to chose who will care for their health and how it should be done.

Yours sincerely

Conella Veldhuijzen

From: Vanessa Verstappen [redacted]
Sent: Sunday, 30 June 2019 10:35 PM
To: medboardconsultation
Subject: Fwd: Consultation on complementary and unconventional medicine and emerging treatments

I choose **Option 1:** "no new regulations are required for doctors practising in the areas of complementary medicine and integrative medicine."

I have chosen to see Integrative Medicine doctors because Conventional medicine provided no answers about why I was sick and I needed medical care with a wider range of diagnostic and treatment options.

I am happy with my GP for simple treatments within brief consultations, but I want to go further with prevention and a deeper understanding of what I can do for myself and my family. My integrative medicine doctor provides me the time and knowledge to do that.

I want more from my doctor. More time. More understanding of causes of illness. More power to understand the ways in which I can improve my health to reduce my need for drugs, surgery and medical appointments. My Integrative Medicine doctor provides these for me in a way that 10 minute consultations with doctors cannot.

Vanessa Verstappen.

Submission for 'Consultation on complementary and unconventional medicine and emerging treatments' to medboardconsultation@ahpra.gov.au

Author:
Edward R. Vickers Diploma of Homeopathy, Diploma of Herbal Medicine.
Registered practitioner with the Australian Traditional Medicine Society.
Email: [redacted]

Thankyou for the opportunity to provide background information on the specifically mentioned complementary treatments of homeopathy and herbal medicine. From the Medical Board proposal there is the possibility that many doctors and medical specialists could be deregistered or reprimanded based on their current use of homeopathy and herbal medicine. I am presuming that the corresponding homeopathic and herbal products could, in time, also be potentially be banned. I am also presuming that other Professional boards (Dental, Nursing etc) would follow the lead of the Medical Board.

Homeopathy

Homeopathy is the use of various 'proven' compounds at different concentrations over the last 250 years. The following is a list of some of the homeopathic medicines in homeopathic materia medica textbooks:
Xrays, BCG vaccinations, Chloramphenicol, Chlorpromazine, Sulfonamide drugs, Cortisone, Ergot drugs, lignocaine, latex, charcoal, atropine, oxygen, sodium chloride, sodium fluoride, coffee, glucose, and many other frequently used compounds amongst the 6,000 listed homeopathic remedies.

Herbal medicine

Herbal medicine has been practiced for thousands of years by many cultures. There are least 2000 herbs with 8000 bioactive polyphenols (also found in food) described in herbal medicine textbooks. Potential herbal / polyphenol products that would conceivably be banned, and doctors deregistered for their use include:
Green tea, black tea, turmeric, coffee, apples, oranges, other fruit, all vegetables, grains including rice and wheat, willow tree extract (aspirin), yew tree (paclitaxel chemotherapy drug), opium poppy, sage, thyme, fennel, rosemary and many supermarket items.

Summary

It is possible every Australian general practitioner and medical specialist could, arguably, be reprimanded or deregistered by the Medical Board. In addition, if other professional boards followed, then all nurses and dentists could be deregistered for their use of IV saline (homeopathic natrum muriatricum) and sodium fluoride (natrum floratum) respectively.

From: Colston Vowles [redacted]
Sent: Saturday, 27 April 2019 5:49 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

Dear Board Members,

I support option 1

Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct).

My reasons are:

The proposed definition of Complimentary and Unconventional Medicine, if adopted, could be used to arbitrarily ban or prevent any treatment that my Doctor and I have concluded would be useful to handle or prevent an unwanted health situation that I may have.

I, and members of my family and various friends, have benefited by using doctors who are integrative or take a holistic approach to treatment. The conventional GP approach is more attuned to only drugs and treating symptoms. The correct approach is to take those steps, wherever possible, that will alleviate and prevent a negative health situation and increase the level of good health.

I, and all members of the public, have a right to choose the medicine or therapy that we receive. I am opposed to any action or regulation that diminishes my ability to obtain factual and reliable information or removes my right to choose how I may best regain and retain good health.

Thank you for receiving this response.

Colston Vowles

From: Janine Wade [redacted]
Sent: Tuesday, 19 March 2019 8:59 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

To whom I may concern

I am sickened that you would want to stop the integrative care that is provided in Australia. It is of the world's best & I have great trust in my doctor. I am thinking of leaving Australia if you take away this service

Janine Wade

[redacted]

From: Dr Akshay W
To: medboardconsultation
Subject: Complementary Medicine Consultation
Date: Monday, 8 April 2019 7:51:04 PM

Dear AHPRA,

Hope this email finds you all doing well.

When we first started in Medical school all bright eyed and bushy tailed, we were trained quite well in extensive biochemistry along with anatomy and physiology. These are considered the foundations of Medical training. Then we got into GP training and we were told to work on SNAP (Smoking, Nutrition, Alcohol and Physical Activity) to help prevent chronic diseases. Although we have been great at working on S, A and P of the SNAP, Nutrition is where we as a community have failed terribly. To make things worse, the rise of instant gratification through social media and "viral" popularity brought bad rap to foods, diets, health "practitioners" that promoted anything to do with Nutrition.

Hippocrates, Father of Modern Medicine, founded the basis of medicine to be optimal food/nutrition to aid the body in healing itself. This was no hocus-pocus. It has been proven thousands of times through plenty of research that optimal nutrition does improve, delay or alleviate the onset or progression of any illness. The industrial revolution that started after the first world war and the accidental discovery of Penicillin in 1928 really changed the course of medicine. Visibly fantastical, modern medicine promised a lot and delivered to a fair degree too. However, we cannot ignore the fact that Penicillin comes naturally from the mould (a naturally occurring fungus!).

The growth of the pharmaceutical industry has been commendable and the need of the time. However, this should not suppress the need to address lifestyle factors. And one of the biggest and constant exposures, in terms of environmental elements, to the human immune system is food. There are plenty of researches done that have concluded an overall reduction in the nutrient density of foods cultivated by modern farming approaches against organic farming. This would equate to the rise in the need for supplementation of certain nutrients where the needs arise to improve one's health status and alleviate signs/symptoms of an illness. On the flip side, there's been an exponential growth in the supplements businesses that have not provided substantial quality information regarding the integrity of their products and hence of questionable value in terms of nutrient distribution when they are ingested. However, there are high end specific nutritional supplements that are only available on a script. Conclusion: We should not be canning the whole profession for the wrongdoings of a few bad apples.

For thousands of years, traditional eastern medicine has held the

importance of looking after the gut microbiome as the highest in the hierarchy of looking at improving one's health. This has been proven (shown evidence for) anecdotally over time. However, in today's day and age of evidence-based medicine that demands running RCTs at an enormous cost to the persons/groups/pharmaceutical companies/Govt funded agencies, needless to say, understandably there are motives behind funding those researches that would yield the agency behind it with at least some profit. Not necessarily monetary profits. A good Integrative practitioner will not undermine the use of evidence-based Western medicine appropriately and when it fails would look into introducing fairly safe nutritional medicine that would adhere to the foundation of medical practice, First Do No Harm.

Although having an Indian background myself, I do not have much training in Ayurveda or Homeopathy. However, I have seen, first hand, the beneficial effects both modalities can have when used in conjunction with Western Medicine. Hence the overarching benefits of utilising the "Best of both worlds" cannot be ignored. However, I would also argue there are practitioners that tout "curative" options that are of unproven benefit and are actually even harmful. Not to mention the emotional and financial costs to the patient seeking those remedies who are in a vulnerable position. So, this is an area where we can expect regulation through a panel with a mix of Integrative doctors and some conventional medical practitioners.

There are reputable Medical Colleges (eg ACNEM) and associations (IFM) striving hard to maintain the integrity of Lifestyle medicine (encompassing of Integrative and Complementary medicine). In an era where more and more countries are supporting Integrative approaches like France, Germany and the USA, it is only regressive to control or banish evidence-based complementary and nutritional medicine just because there are other non-evidence-based alternative therapies that should be regulated better.

For a progressive medical and health industry, I would invoke on the AHPRA to have a better-standardised approach in supporting the advances in Functional and Integrative Medicine while keeping a tab on sham therapies masquerading as curative approaches.

I would also encourage like-minded medical practitioners to come together to participate in a healthy discussion on what's acceptable under the term Integrative and Functional medicine across the developed healthcare systems in the world. I'd appreciate if AHPRA facilitates this process and takes an active role in helping us establish a world-class system of Functional and Integrative medicine that is evidence-based and effective.

References:
1. Let Food be thy medicine.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC318470/

2. Gut Microbiome: https://www.ncbi.nlm.nih.gov/pubmed/?term=gut+microbiome
3. Evidence for Ayurveda: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4995851/
4. Vit C infusions: https://www.ncbi.nlm.nih.gov/pubmed/?term=intravenous+vitamin+c
5. Mind-body medicine: https://www.ncbi.nlm.nih.gov/pubmed/?term=mind+body+medicine
6. Hyperthermia as an adjunct in cancer treatment with chemotherapy: https://www.ncbi.nlm.nih.gov/pubmed/30931666

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Dr. Akshay Wadegaonkar,
MBBS, FRACGP, FARGP, DCH
Integrative & Functional Medicine Practitioner
[redacted]

From: Alyson Walker
To: medboardconsultation
Subject: Submission Re; Alternate Therapies
Date: Monday, 13 May 2019 11:56:41 AM

Submission re: Alternate Therapies.

I want to register my concern that people may not continue to have access to a range of health options, since we are supposed to be a free society, and that they receive support from Medicare for their choices.

A large percentage of the medical profession has been taken over by pharmaceutical companies, so much so that health care is equated, not with curing the cause of disease, but with medicating people with drugs for the rest of their lives. Doctors have become drug prescribers rather than healers, despite the list of dangers listed in drug packet inserts, and the fact that it's been reported that death from properly prescribed drugs is one of the leading causes of death in the USA at least, and probably in similarly-oriented places like Australia. Thousands of people also die each year from mistakes made in hospitals.

Sadly doctors these days are taught little, if anything, of the healing value of foods, herbs, and how to use them to help the body heal itself, which it is amazingly equipped to do.

Many people want to avoid the dangers of filling their bodies with chemical concoctions, especially when drug companies have such a poor record of safety, and a propensity for fraud and corruption.

There needs to be better availability of health care that aims at supporting the body's natural defences and getting bodily systems into balance with better lifestyle choices. The fact that stress is a major cause of disease means that even things like tai chi, yoga, meditation or counselling can be valuable in the healing process.

So many people are suffering from toxic treatments like chemotherapy and radiation when there are natural healing therapies that are safe and are curing people of cancer and other diseases.

People also need access to safer diagnosing methods, as many dangerous methods involving radiation are used instead of safer methods like thermography. I know that, as a woman, I am concerned that mammograms are known to cause harm to twelve people for every person helped, and this is unacceptable when there are safer methods available, but people don't care enough, or aren't well-informed enough, to spend the money providing them.

In a democracy, people should have access to a range of available

choices, and not be forced to accept invasive and unsafe methods of so-called “health” care that hinder or destroy the body’s ability to heal itself. In today’s information age, people have the ability to research their options, and should be supported by the government in doing so.

Yours faithfully,

Mrs Alyson Walker

[redacted]

Christopher P. Walker

Phone/Fax: [redacted]
Mobile: [redacted]
Email: [redacted]

23 June 2019

Executive Officer,
Medical, AHPRA,
GPO Box 9958,
Melbourne 3001.

email: medboardconsultation@ahpra.gov.au

Dear Sir

Unfortunately due to time limitations I am unable to provide an in depth response, at this time, to your call for submissions.

None the less I would like to make known my support for the provision of complimentary and integrative medicine in Australia, including the provision and supply of herbal and nutrient supplements.

I note once again the issue of Lyme disease has been raise. I believe the issue of Lyme Disease really comes down to a nomenclature issue. That is the mainstream medical profession seek to have a formal definition and hence seek to rely on the American CDC definition for Lyme disease whereas there exists a need amongst sick individuals to give some definition to their condition; hence in Australia there exists street terminology for 'Lyme Disease' which is loosely applied to any affliction emanating from a tick bit.

While such terminology differentials can present challenges the refusal to give leeway to patients by the Medical profession is potentially a serious travesty, injustice and divergence from there formal position of "acting in the patient's best interest"[1].

There are many examples where words have different meanings in different territories. For example a) the unit of measure 'Gallon' in UK means 4,546 cubic centimetres and in US 3,785 cubic centimetres[2]; b) the value 'Billion' traditionally was one million million or 10^{12} in UK while in US it was just one thousand million or 10^{9} which the Americans adopted from the French[3].

While there are many more examples of differential meanings worldwide it is inappropriate for the Australian Medical profession to refuse to acknowledge that the Australian street terminology of Lyme Disease does have a different meaning to the US definition.

[1] Role of the Doctor - 2011 - https://ama.com.au/position-statement/role-doctor-2011
[2] Cambridge Dictionary - https://dictionary.cambridge.org/dictionary/english/gallon
[3] Wikipedia - https://en.wikipedia.org/wiki/Billion

Similar arrogance has been demonstrated by some Australian laboratories who claim overseas laboratory results cannot be relied upon since the overseas laboratories are not members of NATA. Such claims are contrary to NATA's position that "NATA accreditation provides the basis for the acceptance of products and services and supports the quality and competitiveness of Australian businesses and industry."[4] In fact NATA participates in the International Laboratory Accreditation Cooperation (ILAC) and "is one of around 100 accreditation bodies world-wide that are signatories to the ILAC MRA."[4] Clearly any overseas laboratory accredited by an similar member to ILAC would have the same standing, credibility and confidence as any NATA accredited laboratory.

Traditional Chinese medicine (TCM) is a style of traditional medicine based on more than 2,500 years of Chinese medical practice that includes various forms of herbal medicine, acupuncture, massage (tui na), exercise (qigong), and dietary therapy[5], but recently also influenced by modern Western medicine.[6] Particularly with a growing Chinese originating sector of the Australian population there is a need and a right to recognise the extensive historical validation for Chinese medicine.

Western Medicine clearly does not have all the answers for if they did there would be no need for ongoing research. Also western medicine and big pharma have had some catastrophic disasters, despite the massive regulation, testing and control. One just need to look at Thalidomide to see how fallible Western medicine can be.

The patient needs and deserves the greatest and most diverse opportunity to get treatment and this should include all forms of complimentary and integrative medicine.

Should the deadline be extended then I would greatly appreciate the opportunity of making a fuller and more detailed submission

Yours faithfully

Christopher Walker

[4] NATA's position in the international arena - https://www.nata.com.au/about-nata/global-trading-network
[5] Traditional Chinese Medicine, National Center for Complementary and Integrative Health - https://nccih.nih.gov/health/whatiscam/chinesemed.htm
[6] Traditional Chinese Medicine, Wikipedia - https://en.wikipedia.org/wiki/Traditional_Chinese_medicine#cite_note-TCMNCCIH-1

From: Sarah Wallace [redacted]
Sent: Friday, 8 March 2019 2:09 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

What you are proposing is to keep symptom treating (of course in ten minutes allocations of time) feeding people high risk pharmaceutical meds to keep them sick and generating income.
Alternate medicine as you call it treats the person and their body/emotions/mental health as a whole. It's also been around for millennia and now, more than ever has the science to back it up.

From: Maria Walsh [redacted]
Sent: Monday, 11 March 2019 12:01 AM
To: medboardconsultation
Subject: Health options

Hi, below is a submission letter to the AMA. The medical board are currently reviewing all holistic and natural therapies including holistic gp's naturopaths etc.
Please look out up and if you feel to, sign and send this, email address medboardconsultation@ahpra.gov.au and pass onto your contacts.
Love
[redacted]

Medical Board Submission
Regarding the public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

As an Australian citizen/resident I feel it's important that I have the freedom of choice in the type of medical care that I use to address my chronic health issues.
I have been suffering from:

Conventional medical doctors have not been able to successfully treat my condition(s) and bring me to a satisfactory level of health.
Pharmaceuticals and the use of conventional methods simply did not work (and in some instances also delivered unwanted side-effects in my case) and, seemed to waste Medicare funds and resources.
It was only when I saw an integrative medical doctor who included lifestyle change, diet and supplements of vitamins and minerals to address my problems that my condition began to improve.
If I cannot see an integrative doctor, or the Doctor is restricted in what he or she is able to prescribe for me, I feel that my health will deteriorate and have a continuing impact on my family, my work, and my wellbeing.
Additional notes:

Concerned,

Name: _____maria walsh_____

Hi, below is a submission letter to the AMA. The medical board are currently reviewing all holistic and natural therapies including holistic gp's naturopaths etc.
Please look out up and if you feel to, sign and send this, email address medboardconsultation@ahpra.gov.au and pass onto your contacts.
Love
[redacted]

Medical Board Submission
Regarding the public consultation on clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments

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If I cannot see an integrative doctor, or the Doctor is restricted in what he or she is able to prescribe for me, I feel that my health will deteriorate and have a continuing impact on my family, my work, and my wellbeing.
Additional notes:

Concerned,

Name: _____maria walsh_____

Signature: _____

Date: ___10/3/19____/_____/_____

Occupation: _____carer_____(optional)
_____

Date: _____/_____/_____

Occupation: _____(optional)

Sent from my iPhone

From: Olivia Walsh [redacted]
Sent: Wednesday, 10 April 2019 12:12 AM
To: medboardconsultation
Subject: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

To whom it may concern
Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.
Specifically, it is alarming that once again Lyme Disease (or Lyme-Like and associated tick borne illnesses) has been called out as an area of concern. It is disappointing to see that Australia is so far behind the latest peer reviewed research in this area, and even more shocking that the Medical Board intend on creating a set of guidelines which will more than likely restrict our highly capable doctors from practising good health care, which is not entirely based on outdated options that come from large pharmaceutical and insurance companies.
Imposing an increase in restrictions through changes to the guidelines will almost certainly stifle innovation and advancement of medical treatment options available in this country, and not just pertaining to Lyme Disease, but to other chronic and disabling illnesses. Australia's medical system will slip even further down the rankings than it already is. Perhaps we should look to progressive countries such as Switzerland who are doing the complete opposite and are encouraging the use of complementary medicines?
I have family and friends who use Complementary, Unconventional and Emerging Medicine and I highly value its availability and I am very happy with its practice. Treating doctors already provide discussion about options for treatment and their relative merits and potential problems. I value free choice in making decisions regarding my own personal medical treatment.
The suggestion of strengthened guidelines is far too controlled, an attack on my human right to seek any treatment I choose to use with my chosen health professional. Whether you agree or not with the diagnoses, the treatment plans, it is not the Medical Board's decision to hold my future at jeopardy because of its own antiquated ideology.
As such, my preferred choice of the proposed outcomes is to retain the status quo, otherwise fellow sufferers will only have the option of travelling overseas, where they are at even greater risk of complications. Australia is not a third world country, and my expectation is that we as Australians should be able to attain the treatment of our choice, here at home.

Your sincerely
Olivia Walsh
9 April 2019

From:	[redacted]
To:	medboardconsultation
Subject:	Feedback regarding public consultation paper
Date:	Monday, 3 June 2019 9:55:13 PM

To Whom It May Concern,

I write with feedback to the MBA about my concern that the MBA is proposing to include Complementary Medicine (including Nutritional and Herbal Medicine) with 'unconventional medicine' and 'emerging treatments' and defined as '*any assessment, diagnostic technique or procedure, diagnosis, practice medicine, therapy or treatment that is not usually considered to be part of conventional medicine. Whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies'.*

I am concerned with the proposed changes in this consultation paper. By grouping Nutritional, Herbal and Environmental Medicine with 'unconventional medicine' conducted by Medical Doctors is to combine different modalities under one collaborative. Examples of 'unconventional medicine' include inappropriate long-term use of antibiotics for viral infections and 'emerging treatments' such as expanding the use of stem-cell therapy are examples that Nutritional, Herbal and Environmental medicine do not have scope to use. Nutritional, Herbal and Environmental Medicine are not qualified Medical Doctors but Complementary Natural Medicine Practitioners and thus do not have the ability for use of these '*approved medical devices and therapies'.* Therefore, the modalities must be differentiated with respect to differing modalities for treatment; largely that Complementary Natural Medicine lacks the use of pharmaceuticals.

Further, I have concern the proposal to group Complementary Natural Medicine with 'unconventional medicine' will create confusion and uncertainty within the public eye and give the impression that Nutritional, Herbal and Environmental medicine are not equally as evidence-based as the rest of the respectable health professions.

Thank you for including my feedback in this quest to fairly differentiate our modalities.

Kind Regards,

Larissa Watt

[redacted]

[redacted].

[redacted]

From: Leonie Watt [redacted]
Sent: Sunday, 23 June 2019 8:06 PM
To: medboardconsultation
Subject: Public Feedback to MBA Proposal

To Whom It May Concern,

I am writing in regard to the MBA requesting feedback from the public on their proposal for tighter regulation on medical practitioners who provide complementary and integrative medicine.

I am concerned about the proposed changes the MBA is advocating in regard to complementary medicine (that include Nutritional and Herbal Medicine) being included with "unconventional" medicine and emerging treatments and defined as '*any assessment, diagnostic technique or procedure, diagnosis, practice medicine, therapy or treatment that is not usually considered to be part of conventional medicine. Whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies'*

I am concerned these proposed changes, if implemented, may lead to health policies that restrict the therapeutic choices available to me and affect my chosen approach (which has proved effective) to maintaining my state of health and well-being.

Nutritional, Herbal and Environmental Medicine is evidenced based, both scientifically and traditionally and regulated. I believe that respect be given to the qualifications and expertise of practitioners in their chosen fields.

Yours Sincerely,

Leonie Watt

Consultation on complementary and unconventional medicine and emerging treatments.

Prior to addressing questions and issues of concern, there are a number of areas within the consultation paper itself requiring further clarification and transparency:

1. Members of the public are basing their feedback on the discussion paper provided, yet it is clearly stated that "*if approved, the guidelines. . . .will not include the examples currently in the discussion paper."* (p3 Public Consultation Paper) This is confusing and needs further clarification. As the guidelines, if approved, are to be a **standalone document**, the Board can update supporting documents that outline the scope of the guidelines when required. **It's unclear as to whether the Board would seek public consultation to do this and what exactly would be included in this supporting documentation?**

2. When presenting the **two options** for consideration (p2 Public Consultation Paper and p17 Discussion Paper), Option 2 outlines that the guidelines will *"clearly articulate the Board's expectations of all medical practitioners and supplement the Board's Good medical practice: A code of conduct for doctors in Australia."*

   Although the *"Board's approved code of conduct"* is mentioned in Option 1, it is not given in the same detail. All doctors must currently practice under the *"Board's Good medical practice: A code of conduct for doctors in Australia"* and **this should have been clearly and equally outlined in both options, not just in Option 2.**

3. Option 2 states that there would be a strengthening of the current guidelines through *"practice-specific"* guidelines that "*clearly articulate the Board's expectation of all medical practitioners and supplement the Board's Good Medical practice: A code of conduct for doctors in Australia."* (p2 Public Consultation Paper and p17 Discussion Paper)

   The current guidelines already provide for this and there is a lack of transparency regarding what ***"practice-specific"*** actually means? This could be accurately or inaccurately interpreted as restricting a doctor's autonomy to use their skills, knowledge and abilities to provide individualised healthcare, thereby disadvantaging the patient?

4. Throughout the documents, reference is given to *"concerns being raised by stakeholders"*, yet these stakeholders are not actually identified. Further explanation could have been given here.

   Independent response to the consultation has highlighted that the peak medical organisations of complementary medicine were not consulted prior to the paper being released and surely they would have to be considered key stakeholders.

5. In the proposed definition, complementary medicine, unconventional medicine and emerging treatments are all inclusive when there is no real explanation or reasoning given for this. Unconventional medicine and emerging treatments have considerably more risk than complementary medicine, which is an evidence-based functional approach to health care, practiced by qualified doctors, and often used in conjunction with and to complement conventional treatments.

   There is also a lack of definition of *what does* constitute conventional medicine and this should have been outlined in the paper.

Address to Issues of Concern

The Board has identified the following issues of concern:

"Patients being offered and/or having treatments:

- *For which the safety and efficacy are not known*
- *Which may be unnecessary*
- *That expose them to serious side-effects, and*
- *That may result in delayed access to more effective treatment options"*
  (p2 Draft Guidelines)

We are all in a time of individualised health care, mainly due to the fact that there are growing numbers of patients presenting with complex and chronic symptoms that conventional medicine alone simply cannot keep up with. Patients are more researched and have access to more information than ever before which is why so many people take up complementary treatments. These practices are integrated to complement conventional medicine and treatments to achieve the best possible outcome.

All the above concerns could certainly be raised about conventional medicine and treatments as well. A tried and tested prescription drug, for example, may be completely safe for one person but may have serious side-effects for someone else and may also be unnecessary. The possibility for delayed access to effective treatment options can exist across **all areas of medicine** and **all doctors** are required to give sufficient information on available treatments to enable patients to make educated decisions about their health care.

If anything, patients receiving complementary and integrative medical treatments are possibly more aware and equipped with information about medications and treatments than patients receiving conventional treatments alone. This is possibly due to the need for individual research and awareness as well as time available during consultations.

The Discussion Paper also outlines concerns of the following:

- *"Insufficient information provided to patients*
- *Inappropriate tests being ordered*
- *Inappropriate prescribing*
- *Inappropriate treatments"*
  (p3 Discussion Paper)

Again, all of the above concerns can be raised across the board with conventional medicine as well. For instance, how many times are antibiotics prescribed when the illness has already run its course? How many times have the results of blood tests not fully been explained? How much information is really given to the patient if they don't come to an appointment armed with their own set of questions?

In the Discussion Paper (p7) under *'Concerns about therapies and treatments being offered'*, a point raised is the *"prescribing of compounding products where a commercial product is available and suitable"*. Should a doctor be expected to suggest a generic vitamin/mineral supplement, for example, just because it's commercially available? This point is then contradicted with another concern regarding the *"prescribing of compounding products that have been manufactured in bulk rather than to meet an individual's needs."* It should be noted that commercially available products *are* usually manufactured in bulk.

While some compounding products are readily available, they are also made to suit an individual prescription and are made under strict quality assurance guidelines.

It is clearly stated in the Discussion Paper that Option 2 would have only *"minor impact on practitioners and consumers and would provide the greatest benefits to the community."* (p18 Discussion Paper)

I personally don't understand how something that is to have only *'minor impact'* could possibly have the *'greatest benefit'*. There seems to be an inherent contradiction here. I also don't understand why the Board would produce a discussion paper of this nature with a preferred outcome that would bring only *'minor'* change. I think this only strengthens the argument for retaining the status quo and continuing to uphold Option 1, which outlines **one set of good practice guidelines for all doctors to follow**.

Draft Guidelines

Out of the 9 points of guidance in the Draft Guidelines (p4 – 8 Draft Guidelines), there is only 1 guideline written for "*all registered medical practitioners, including doctors whose patients use complementary and unconventional medicine and emerging treatments, but who don't themselves provide these treatments"* which relates to number 1. Discussion with patients. The remaining 8 guidelines are **only** for "*registered medical practitioners who provide complementary and unconventional medicine and emerging treatments."*

Many of the guidelines outlined could easily apply to any practicing doctor and not just those who practice complementary medicine. Surely conventional doctors have the same responsibilities when it comes to patient education, disclosure of information and options of treatments available.

In guideline 9, Research and advancing knowledge, 9.2 states that doctors providing complementary medicine should be *"prepared to contribute to and share new knowledge with the profession."*

Integrative medical practitioners spend countless hours of hard work and dedication to contribute to public discussion, parliamentary enquiries and the like, bringing their own knowledge, experience, evidence and case studies to the attention of those who have the ability to facilitate change. More often than not, these highly educated and professional practitioners are ignored under the guise that there is insufficient evidence to do anything different. I find it disheartening and somewhat ironic that even this has had to be written into a guideline.

Throughout the Discussion Paper and the Draft Guidelines, there is a wide-ranging and comprehensive definition of what constitutes the term *"Practice"*.

*"**Practice** means any role, whether remunerated or not, in which the individual uses their skills and knowledge as a health practitioner in their profession. For the purposes of these guidelines, practice is not restricted to the provision of direct clinical care. It also includes using professional knowledge in a direct non-clinical relationship with clients, working in management, administration, education, research, advisory, regulatory or policy development roles, and any other roles that impact on safe, effective delivery of services in the profession."*

It could be argued that the expanse of this definition is overly restrictive and gives the impression of *'covering all bases'* from a legal perspective rather than any other.

In Conclusion

I support the continuation of status quo retained under **Option 1**, where all medical practitioners comply with the *Board's Good medical practice: A code of conduct for doctors in Australia.* **There should be one code of conduct for all medical practitioners**.

At a time when integrative and conventional medicine are coming together more and more, there would be nothing served in creating an *"us and them"* approach, particularly from a patient's perspective.

Complementary medicine should not be included in the same definition as unconventional and emerging treatments.

Thank you for considering my submission to this consultation and response to concerns that have been raised.

Kind regards

Andrea Weber

Date: 17th June 2019

From: [redacted]
Sent: Tuesday, 11 June 2019 12:09 PM
To: medboardconsultation
Subject: The value of integrative medicine

Hi Medical Board Consultation Group

There are concerns that integrative medicine wont be valued during your consultation process. My personal experience and research has found it to be an excellent part of primary healthcare. My own health has improved significantly over the last few years, under the guidance of my GP as I have adopted a healthier diet and lifestyle. A healthier population will reduce the burden on the healthcare system. Obviously improving regulation will improve patient safety. I hope you will value the contribution of integrative medicine to primary healthcare and consider the following points during the review:

- The grouping of integrative medicine with 'unconventional medicine' and 'emerging treatments' may create the impression of being "fringe" rather than evidence-based
- That many of the terms used in the rationale such as 'unconventional medicine', 'inappropriate use' and 'emerging treatments' leads to ambiguity and uncertainty
- That the term 'complementary medicine' also includes access to traditional medicines
- No evidence produced in the discussion paper quantifies risk in practicing complementary or integrative medicine vs 'conventional' medicine
- That there was NO consultation with the Integrative Medicine or complementary medicine community before the document's release
- That the current Good Medical Practice: A Code of Conduct for Doctors in Australia already adequately regulates doctors' practise and protects patient safety. There is no need or justification for a two-tiered approach
- That the right of patients to determine their own medical care is under threat
- That the lack of clarity on how to determine what is 'conventional' versus 'unconventional' can be misused by people with professional differences of opinion which results in troublesome complaints

Kind regards

David West
RN [redacted]
---- [redacted]

From: Susan Whittaker [redacted]
Sent: Thursday, 4 April 2019 7:18 PM
To: medboardconsultation
Subject: Integrative Medicine

I vehemently object to the Medical Board discontinuing Integrative Medicine as a practice as well as Compounding pharmacies. I have been using both these for the past 7 years and am feeling much better than when I went to 15 General Practitioners in Australia who had no idea what was wrong with me and just wanted to prescribe useless Big Pharma medication. All General Practitioners are brainwashed by Big Pharmaceutical companies and are paid to prescribe certain medicines especially [redacted] Even a Representative from [redacted] told me this while I was in a General Practitioners waiting room.

By not taking big Pharma medicine I am saving the Australian Government thousands of dollars as I do not have side effects of these medications and I never wish to take them.

I strongly suggest you do not be so highly influenced by money making schemes that the Big Pharmaceutical company have obviously bribed you with.

I, along with hundreds of thousands of people, will protest against the medical board if this is put forward.

Kind regards

Susan Whittaker

From: [redacted]
Sent: Monday, 8 April 2019 5:45 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Hi,

I've read the Medical Board of Australia's proposal and am concerned .

I don't believe combining the definition of complementary medicine with unconventional medicine and emerging therapies is reasonable. There are different risks and benefits between them.

I want to be able to ask a scientific opinion and advice from my GP on complementary medicine.

I don't believe the current proposal achieves this and would recommend no change without significant changes to the proposal

Kind regards

Matthew Whitting

From:	Rod Willett
To:	medboardconsultation
Cc:	[redacted]
Subject:	Public consultation on complementary and unconventional medicine and emerging treatments
Date:	Sunday, 3 March 2019 5:28:09 PM

Dear Sir/Madam

The proposals in the consultation paper are reasonable and I am in support of strengthening the regulation.

My greatest criticism is the lack of equality of these standards across the professions registered by AHPRA.

Example 1: A GP counselling against vaccination would be seen as inappropriate and open to disciplinary action. A chiropractor can voice these sentiments without fear of reprisal (and does so regularly).

Example 2: A GP performing spinal manipulation to treat influenza would be deemed unacceptable. A chiropractor can do so.

Example 3: A pharmacist can sprout the benefits of nonscientific homeopathy or vitamins etc and even up-sell during a prescription service. This wold be unacceptable for a GP.

Example 4: A pharmacist can co-locate and/or condone the services of an iridologist or naturopath etc if they wish. I suspect these services in a GP would be considered a conflict and be unacceptable.

I would like to see scientific evidence based standards normalised across all professional groups.

To target groups with different standards is biased and unacceptable in today's evidence based world.

Kind regards

Rod.

Dr Rodney Willett ***MBBS FRACGP***

[redacted]

[redacted]

[redacted]

[redacted]

From: Aliya Williams [redacted]
Sent: Wednesday, 27 March 2019 2:18 PM
To: medboardconsultation
Subject: : 'Public consultation on complementary and unconventional medicine and emerging treatments'

I am totally against this I believe that people should freely be able to choose the medical treatment they require wether pharmaceutical or natural. There is no reason to not allow the "unconventional" medicines to be an option. Whatever is in the best interest and choice of the patient it should be up to the individual not forced by a health care system that is clearly looking after their own interests and not the interests of the patient.
Thank you

From: Janelle Williams [redacted]
Sent: Wednesday, 10 April 2019 10:16 PM
To: medboardconsultation
Subject: RE: PUBLIC CONSULTATION ON COMPLIMENTARY MEDICINE AND EMERGING TREATMENTS

Executive Officer
Medical - AHPRA
GPO Box 9958
Melbourne VIC 3001

To whom it may concern
Please consider this letter a formal submission in response to the Medical Board of Australia's proposal to strengthen the guidelines surrounding medical practitioners who provide complementary and unconventional medicine. I am highly concerned at these proposed changes and do not agree with them for reasons which I will attempt to outline below.
Specifically, it is alarming that once again Lyme Disease (or Lyme-Like and associated tick borne illnesses) has been called out as an area of concern. It is disappointing to see that Australia is so far behind the latest peer reviewed research in this area, and even more shocking that the Medical Board intend on creating a set of guidelines which will more than likely restrict our highly capable doctors from practising good health care, which is not entirely based on outdated options that come from large pharmaceutical and insurance companies.

Imposing an increase in restrictions through changes to the guidelines will almost certainly stifle innovation and advancement of medical treatment options available in this country, and not just pertaining to Lyme Disease, but to other chronic and disabling illnesses.

Australia's medical system will slip even further down the rankings than it already is. Perhaps we should look to progressive countries such as Switzerland who are doing the complete opposite and are encouraging the use of complementary medicines?

I have family and friends who use Complementary, Unconventional and Emerging Medicine and I highly value its availability and I am very happy with its practice. Treating doctors already provide discussion about options for treatment and their relative merits and potential problems. I value free choice in making decisions regarding my own personal medical treatment.
The suggestion of strengthened guidelines is far too controlled, an attack on my human right to seek any treatment I choose to use with my chosen health professional. Whether you agree or not with the diagnoses, the treatment plans, it is not the Medical Board's decision to hold my future at jeopardy because of its own antiquated ideology. As such, my preferred choice of the proposed outcomes is to retain the status quo, otherwise fellow sufferers will only have the option of travelling overseas, where they are at even greater risk of complications. Australia is not a third world country, and my expectation is that we as Australians should be able to attain the treatment of our choice, here at home.

Your sincerely
Janelle Williams
10-4-19

From: [redacted]
Sent: Thursday, 4 April 2019 9:13 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments
Attachments: [redacted]

Dear Medical Board,

RE: Consultation on complementary and unconventional medicine and emerging treatments

I am writing as a certified Building Biologist who performs 4 to 6 home / work place assessments per week in the Sydney region. The majority of my clients are referred to me by their health professional because they have concerns that their environment at home or at work is one of the underlying factors in their chronic illness. In almost 100% of the assessments I undertake I find that there are environmental factors that are impacting the occupant's long term health. If these people had not had access to integrative health professionals the chance is they would not understand the impact of their home or work environments on their health. Indeed having these assessments (at great personal cost not covered by Medicare rebates) will ultimately result in reduced ongoing medical costs and an overall reduced burden on our health care system.

Twenty-four percent (24%) of the population do not have the immune response gene to create antibodies to bio toxins created in a water damaged building. This means that while 76% of the population may not experience adverse health effects living in a water damaged building, the remaining 24% can potentially experience adverse health effects.

Please do not make it more difficult for health practitioners practicing Integrative Medicine to work with these people who so desperately need help.

Kind regards,

Jeanette Williams
Building Biology Sydney
[redacted]

From: Marilyn Williams [redacted]
Sent: Wednesday, 22 May 2019 8:06 AM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments'

To whom it may concern,

I support Option 1.

I think we all should have the choice of how we take control of our own health.

I think functional/integrated doctors have all the tools in there kit - they can adopt conventional treatment when it is deemed the best option but have the training and knowledge to implement preventative and complementary treatment when more suitable.

I personally have experienced both and without a doubt the integrative/functional approach has been life changing for me.

Please don't restrict these incredibly well trained and knowledgeable doctors from providing the much sought after service they provide.

Marilyn Williams
[redacted]

From:	Jenna Wilson
To:	medboardconsultation
Subject:	Submission
Date:	Thursday, 28 March 2019 7:46:58 PM

"To whom it may concern;

My name is Jenna Wilson Occupation: IT/ Programmer. As an Australian citizen I should have the right to choose the methods I use to address my chronic health issues. I have been suffering from multiple chronic illnesses. Conventional medical doctors have not been able to successfully treat my condition(s) and bring me to a satisfactory outcome. Using a G.P. prescribing pharmaceuticals and the use of conventional methods that simply did not work (and in some instances also delivering unwanted side-effects) has been a complete waste of Medicare funds and resources. Until I saw an integrative medical doctor who included lifestyle change, diet and supplements to address my problems, my condition gradually became more chronic until I was forced onto a disability pension. It's only thanks to integrative medicine that I can see hope of regaining my health and returning to work in future. If I cannot see an integrative doctor, I am absolutely certain that my health will deteriorate and have a continuing negative impact on my family, my work, my well being, not to mention being a complete and utter unnecessary waste of the tax payer dollar.

Jenna Wilson

From: Miles Wilson-Greene [redacted]
Sent: Friday, 3 May 2019 2:58 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

Questions for consideration

Support Option 2

1. I do not agree with the terminology at all. I would recommend “Unproven practice”, being that all the thing which are looking to be covered by these are both not medicine, and not therapy (https://www.merriam-webster.com/dictionary/therapy ->medical treatment)
2. I do not agree. The use of “conventional” medicine suggests that there is “unconventional” medicine. This is not the case. There is medicine and NOT medicine. Please either remove the conventional or add the appropriate wording on “proven peer reviewed” medicine. This could also be used to identify “off label” usage due to the lack of proven peer reviewed (though if something is off label, shouldn’t it’s use be studied further to validate the off label usage?)
3. No comment.
4. The insurance impacts of giving any form of legitimacy to non-medical “Unproven Practices”
5. Yes. Any such practice which does not initiate the conversation about treatment with “Have you talked to a real medical doctor about these issues. This practice is not proven to have any positive health benefits.” Should be illegal.
6. No Comment.

- Miles

PS. Sorry if this form usage is in correct. Your website was very unclear about if this was a satisfactory method to submit a normal submission. Setting up a webform for easy submission would be really useful.

Additionally, Is there any legislation which would force cases like this https://www.yourhealthyourchoice.com.au/mba-submissions/ to provide actual links back to the general, not filled in automatically with crazy non-medicine page? It was difficult identifying which thing to support to counter the people who believe that non-medicine should be given any credibility at all.

From: Simone Winchester [redacted]
Sent: Wednesday, 26 June 2019 11:22 AM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Dear MBA,
PLEASE DO NOT lump together ‘complementary medicine with unconventional medicine and emerging therapies’ into a single definition. They’re not the same.

About 30% of Australian GPs utilise some aspect of complementary medicine within their medical practice; it could even be argued that this is current conventional medicine. These are highly trained, specialist doctors educated beyond their medical tertiary qualifications.

As in any profession there are good and bad practitioners. We can’t have one rule for some practitioners and one rule for others. The key is ensuring regulation is focussed on the health and safety of ALL Australians. There should be only ONE set of good practice guidelines that ALL doctors should follow.

This is a step backwards in time and an indictment on the progress of healthcare in Australia. We need to be open to taking a holistic approach to treatment and embracing new and innovative medical practices.

Do NOT limit MY choices as a patient. Please register my objection to your proposal.

Kind Regards,

Simone Winchester

[redacted]

[redacted]

[redacted]

From: [redacted]
Sent: Friday, 28 June 2019 1:21 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Dear MBA,

I choose Option 1...
I'm open to both conventional and complementary medical treatment and doctors should be too. If anything, the MBA should be looking at penalising doctors who DON'T practise or support integrative medicine as they are negligent if they don't explore both non-drug and drug approaches for managing my health and illness. This is what the community wants; it's time for outdated doctors and the MBA to face up to this reality, get educated; or resign.

Also, it's CRIMINAL that The Medical Board of Australia includes members of the Friends of Science in Medicine, a political lobby group opposing Complementary Medicine and Integrative Medicine. This is a clear conflict of interest. The Medical Board of Australia should cancel the current consultation, and go back to the start with all current and past members of the Friends of Science in Medicine lobby group excluded from Board participation.

Regards,
Mikael Wolf

From: Tracey Woods [redacted]
Sent: Thursday, 27 June 2019 9:41 PM
To: medboardconsultation
Subject: 'Consultation on complementary and unconventional medicine and emerging treatments

Hi
I am writing to request that patients continue to have freedom of choice in relation to the care and treatment they wish to receive, including integrative care options.
My family and I have faced significant health challenges which were unable to be addressed through conventional medicine. I was only able to recover the health of my family through consultations with various integrative health professionals.
The outcomes of these approaches have assisted me to manage conditions without the use of pharmaceuticals, as well as being able to avoid unnecessary surgery.

I would like to express my support for Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

thank you
Tracey Woods

From: Michelle Woolhouse
To: medboardconsultation
Subject: submission relating to consultation on complementary and unconventional medicines.
Date: Tuesday, 5 March 2019 11:17:02 AM

To Whom It May Concern:

I write this submission as the medical director of Whole Medicine. Whole Medicine is an integrative medicine practice that has been in operation for over 10 years and has had over 10,000 patients attend the clinic during this time. We have used and implemented a holistic and evidence based model of care during this time.

As an evidence based medical (EBM) practitioner I would like to remind the board of the broad definition of the evidence based model designed by Prof Sackett in 1997. The EBM model was medicine based on the current evidence at the time, but which also included the clinicians experience and the patient's values and beliefs. It is the latter 2 aspects of EBM, which I feel the medical profession needs to be reminded of throughout this review process.

The current evidence available to us, provides us with the scientific background to support and lead our choices, but as Medicine is an art, informed by science (not a pure science), we are at risk of creating a huge limitation on the profession if we practice within the confines of pure science without the recognition of the vast differences in humanity we see within our GP communities.
Humanity and individual humans are intricate, complex beings, whose culture, beliefs, parental nurturing, past experiences, education, nutritional, mental, emotional, spiritual and environmental factors all play a role in the definition of health for that person. Because of this multi-factorial unique imprint of each individual, means that there is no way our current scientific thinking and research methods can account for all of those variables; hence it's inherent limitations.

I am concerned about the variety of definitions presented in the draft document as the overriding definition for the board to make judgement on. At Whole Medicine, we have always adopted the AIMA definition of integrative medicine and as such this allows us to expand our approach within the evidence base. But I must also remind you that not everything we practice has been learned in medical school: I was educated regarding the evidence and usage of St Johns Wort for mild to moderate depression at a post graduate RACGP approved event, I am aware many of my colleagues would consider the usage of this herb as outside the conventions of Western medicine.

I would very much hope that it is not the intention of the board to exclude any safe, evidence based nutraceuticals or herbal medicine (such as saw palmetto, cranberry, ginger or st johns wort) from the clinicians medical tool box as that would be a gross travesty in patient centred care, which is why the definition that is adopted by the board is of such critical importance. To combine the vastly different practices of "complementary medicine" *and* "unconventional medicine" *and* "newly emerging

medicine" in the same definition is potentially problematic and in my opinion would lead to very different outcomes.
I am sure you are aware of the depth of the complexity of the role of the GP in our current medical system in addition to the logarithmic increase in medical literature over the past few decades; so much so of an increase , that it is scientifically impossible to be across it all as a modern medical practitioner and therefore there will naturally be an inclination for certain interests of that practitioners to be emphasised in their work based on their patient population. For example my patient base are interested in natural, non drug therapies as first line treatments, where as other patient populations are keen on pharmaceuticals as first line. My patient base is non refugee based, so my knowledge in that area is deficient compared to some of my colleagues who practice in a refugee based area. By placing restrictions on a practitioner's ability to seek further evidence-based knowledge has the potential to stifle the creativity and innovation of the profession. This has the potential of increasing burnout risk for the GP and mistrust in the profession from the community, which is worryingly on the rise.

We must remain conscious of the values and beliefs of our community and recognise the increase of usage of over the counter nutrient and herbal medicine is above 65% of our population, and 50% of all Australians attend a non conventional health practitioner in any given year. To set rigid boundaries on the scope of General Practice risks polarising those in the community who favour a more natural approach to their health care.

When a patient comes to us refusing chemotherapy as an example, we work with their beliefs, their anxiety, their cultural understanding to create a collaborative, cohesive and rapport based relationship that we can work together to achieve a desired outcome. It is important that that person is engaged, supported, and their beliefs held in trusted care.

I am concerned in reading the draft submission that the board has already made up their mind in their preferred next step and would like to request the names and the post-graduate qualifications of the board, most importantly does anyone of the assessment committee have any post graduate qualifications in integrative medicine?

I am concerned at some of the case studies that have been put forward regarding newly emerging therapies and other dangerous scenarios and agree there needs to be some safe guards in place to protect the professions reputation and the public's safety but I implore you to explore the great work integrative doctors do for the community and would like to extend you an invitation to our clinic, if you are looking for an example of safe, kind, compassionate, holistic and evidence based medicine.

Yours sincerely,

Dr Michelle Woolhouse
MBBS, FRACGP, FACNEM, FASLM

From: [redacted]
Sent: Thursday, 27 June 2019 2:55 PM
To: medboardconsultation
Subject: Public consultation on complementary and unconventional medicine and emerging treatments

Dear Medboard Consultation,

I wish to submit my commitment to the ability to choose the use of holistic treatment for my health and wellbeing. At the age of [redacted] I have found that this method of treatment has been highly successful for the majority of my life. I believe Australians should have the right to choose whichever treatment they find successful. The complementary and unconventional medical industry is a highly professional addition to the Australian way of life today.

Yours truly,
Kathleen Wyborn

From:	Weixing Yan
To:	medboardconsultation
Subject:	Consultation on complementary and unconventional medicine and emerging treatments
Date:	Thursday, 18 April 2019 4:49:05 PM

It is right decision that you are doing now.

I am original trained as a medical doctor. Then I spent 4 years to learn naturopathy which I believe helping people to keep fit and healthier.

Doctors and GPs are trained in Medical system that makes diagnosis and prescription or surgery forpatients. They are not able to give a detailed lifestyle, nutritional or hebal treatment plan though they can give these suggestion to their patients. For example most GPs tell a patient with hypertension to reduce stress, stop smoking, do exercise but They Do not Give How to reduce stress, What type exercise patient do or how long or how often exercise to do. These all detailed plan should be given by a well trained naturopath or nutritionist or medical exercise specialist. These integrative management of multiple professionals can provide a quality health service.

Regards,

Weixing Yan
BMed, MD, PhD and Adv Dip Naturopathy

From: Stephen Yeo [redacted]
Sent: Monday, 22 April 2019 8:57 PM
To: medboardconsultation
Subject: Fwd: Feedback for Consultation paper

Begin forwarded message:

From: Stephen Yeo [redacted]
Subject: Feedback for Consultation paper
Date: 1 April 2019 at 2:03:06 pm AEDT
To: medboardconsultation@ahpra.com.gov.au

To Whom It May Concern,

I have recently been made aware of a "paper" which has been released by the MBA which has an adjender to redefine what is 'safe medical practice' in Australia.

It is absurd to consider guidelines becoming regulations to attempt to illiminate practitioners who "step outside" guidelines that have been totally acceptable since 1946. Even more irrational to attempt to silence free speech.

This is a violation of the rights fo Australians to have the highest attainable standard of health. I believe it also violates the right of self determination and protection of the rights to freedom of thought, conscience and to freedom of opinion and expression.

We need to be able to continue to exercise the freedom to choose the practitioner and managed treatment of our choice.

I and two of my children have obtained advice from an extremely well educated practitioner, and have and still are taking supplements and our health has improved to much better levels without the need for government supported pharmaceutical medicines. We now, in fact, make less trips to a GP for health complaints than I ever have.

It is unethical and ludicrous to allow the powerful and well financed pharmaceutical industry dictate to the Government and regulatory authorities the direction for the Australian medical industry. It is also morally questionable the ethics involved to attempt to bankrupt and eliminate manufacturers, and suppliers of supplements in Australia.

I object to this paper 100%

Regards

Stephen Yeo

The Medical Board of Australia

Response to the public consultation on “Clearer regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments”

I choose Option 1.

About myself

I am an integrative medicine practitioner. I graduated from the University of London in 1999 and obtained membership with the Royal College of Physicians. I then obtained a Masters degree in Nutrition. I see patients who have chronic conditions, mainly metabolic syndrome, obesity, autoimmune disorders, chronic fatigue, allergies and environmental sensitivities, anxiety, burn-out, digestive disorders and chronic pain. I use a combination of lifestyle modifications, dietary measures and safe, evidence based nutritional supplementation – vitamins, minerals, probiotics, prebiotics where indicated. These patients are relieved to have a doctor listen to them and take the time to do a very detailed assessment. Most are interested to learn of alternatives to taking prescription drugs for symptom relieve only and being educated on why/ how their health problems could have arisen. They are looking for a better quality of life and to explore what other safe and evidence informed treatments are available for them, such as optimizing their gut microbiome, their sleep quality, their breathing and understanding the impacts of trauma and stress on their immune and nervous systems.

As a doctor who believes in partnering with their patient for long term health comes, using natural therapies, reducing pharmaceuticals wherever possible, educating on nutrient and lifestyle, running patient groups, working with health coaches and believing that community is medicine more than what I learnt at medical and post graduate training, I believe I am subjected to and a target for the Medical Board’s new proposed guidelines, as I am possibly not considered ‘conventional’. Equally I do not consider myself as practicing “unconventional, complementary or emerging

treatments", but practicing evidence based lifestyle, nutritional and environmental medicine.

The Medical Board clearly states a preference for changes to the code of conduct, the implications of which are not clear and the definitions have created a great deal of anxiety both for the profession and patients concerned about what these changes could mean. Integrative, lifestyle, nutritional medicine practitioners could be restricted unduly and patients would lose access to the care they choose.

Integrative medicine is important and has its place in 'conventional medicine'

Patients who choose to see integrative medicine doctors have multiple complex health issues that severely impact on their lives and work. Their problems are often undiagnosed or given descriptive labels that describe a cluster of symptoms for which a specific treatment can be offered, but without understanding the underlying reason for the problems. These conditions include irritable bowel syndrome, chronic fatigue, fibromyalgia, chronic pain, autoimmune disease and mood disorders. Many of these patients have several of these diseases and not because they have many separate conditions but because they have pre-disposing and precipitating factors that have resulted in their health problems.

Most have seen many doctors over years without explanation or relief for their health problems. They have either been told that there is nothing wrong with them, that their tests are all normal or that there is nothing that can be done other than treating their symptoms with medications -analgesics, immunosuppressants, anti-depressants and other medications. These medications and their interactions cause other health issues for many people.

The field of nutritional medicine has greatly expanded in recent years. It is based on understanding of cellular metabolism, biochemistry, physiology and microbiology. The research and publication of peer-reviewed literature is increasing exponentially. There are university departments around the world researching and teaching in this field of medicine.

Unfortunately in Australia this knowledge has not been incorporated into undergraduate or postgraduate teaching. Undergraduates report a lack of nutrition education in their training (1,2) and this translates to a lack of knowledge and confidence of qualified doctors to discuss and counsel patients on food and nutrition (3). This is very concerning as non- communicable disease is the biggest cause of mortality in the developed world and most of that disease burden is due to diet and lifestyle. There are enormous economic ramifications of not practicing preventative medicine with the cost of end stage care impacting on all economies.

Most integrative doctors practice in a way to minimise harm from conventional drugs and polypharmacy. Most integrative doctors, particularly GPs see their patients as a whole, and help their patients strive for a state of health, rather than to simply treat symptoms of a disease. The WHO definition of health is *''a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity* ".

Unfortunately, this concept of health is generally ignored by our imposition of our bio-medical model of ''evidence based'' conventional medical care and very little of the social environmental determinants of chronic disease comes into the paradigm of 'Conventional Medicine' practice. Medicare and bulk billing/ 10-minute medicine serves acute medical care needs well, but longer appointments and integrated approaches to chronic disease is a major part of the solution for most patients who are not satisfied with prescription-pad medicine.

<u>Concerns about the proposed regulations:</u>

The Australasian Integrative Medicine Association definition of complementary medicine is possibly the most accurate of those in the Medical Board document: a philosophy of healthcare…combining the best of conventional western medicine and evidence-based complementary medicine and therapies within current mainstream medical practice.

Accepting the medical board's proposed definition means accepting that the current

version of ''conventional'' care over and above other forms of care prevalent in this country is fraught with ethical, moral and legal issues. There are numerous traditions of "conventional medicine'' around the world where a different mix of traditions of health care and science/ evidence-based care are practiced.

In a multicultural society such as Australia, it is unethical to require a different expectation of level of evidence for other conventions of medicine that are different to our own Western tradition of "Conventional Medicine".

The potential significant discrimination against both communities and healthcare providers whose paradigm extends beyond the biomedical paradigm, under this proposed definition, introduces the real potential for significant oppression of alternative approaches to healthcare.

Combining this biomedical bias of conventional medical practice with a different standard of scrutiny (as suggested by Option 2) for those providing more holistic approaches to healthcare, to those providing conventional medical care has the potential to impair the basic human right to freely access health care consistent with the persons choice or model of health. It discriminates against those in Anglo-European and other cultures who may seek out lifestyle and natural approaches to their health care such as using nutrients, herbs, acupuncture, yoga, psychological and spiritual support.

Medicine is in constant flux and subject to rapidly changing evidence- who is to name what is 'emerging' or not? Stifling this is akin to blocking the advancement of science and medicine.

The only concern of the Medical Board of Australia in this process is, and should be, *safety*. The Chair Anne Tonkin has said this publicly. Questions about *how effective* Complementary Medicine and Integrative Medicine practices are should not be dictated by the Medical Board or medical professionals without expertise in this, but instead should come from the respective colleges and specialist interest groups. A very

robust discussion can be had about the *relative risk* of conventional medicine practices over integrative approaches. Extensive evidence regarding these facts have already been provided by numerous other submissions.

The medical board needs to be transparent and specific about the apparent concerns over 'complementary and emerging therapies', as the cases cited in the Discussion Paper by no means refer to what complementary or integrative medicine practitioners do. Further more, and most importantly, the current Good Medical Conduct guidelines sufficiently cover for these concerns, which apply to all doctors.

In conclusion

As a concerned doctor and board member of the Australasian College of Nutritional and Environmental Medicine, and committed to better health outcomes for the Australian community, I urge the medical board to consult with the profession, listen to concerned consumers and avoid the onerous effect of over-regulation. In the current medical climate, this would restrict access to safe and effective health care options.

There has not been any demonstrated need to regulate Complementary Medicine or Integrative Medicine. These are safe practices that need no additional regulation, especially where the definitions are highly flawed and should not be used in a regulatory environment. I select option 1.

Dr Christabelle Yeoh
MBBS MRCP MSc (nutrition)
[redacted]

1) Devries S, Willett W, Bonow RO. Nutrition Education in Medical School, Residency Training, and Practice. *JAMA.* Published online March 21, 2019321(14):1351–1352. doi:10.1001/jama.2019.1581

2) Mogre V, Stevens FCJ, Aryee PA, Amalba A, Scherpbier AJJA. Why nutrition education is inadequate in the medical curriculum: a qualitative study of students' perspectives on barriers and strategies. 2018;18(1):26. Published 2018 Feb 12. doi:10.1186/s12909-018-1130-5

3) Danek RL, Berlin KL, Waite GN, Geib RW. Perceptions of Nutrition Education in the Current Medical School Curriculum. Fam Med. 2017 Nov; 49(10):803-806.

From: Tamara York [redacted]
Sent: Tuesday, 12 March 2019 9:54 AM
To: medboardconsultation
Subject: Complementary medicines

To whom it may concern,
Dear Sir/Madam,

I am appalled that you are considering banning some complementary medicines, we live in a free country where I have the right to use homeopathic medicine if I choose to do so. You have no right in banning something because you don't agree with it. The entire Royal family use homeopathic medicines and many mainstream doctors prescribe it in the UK and Europe. It is non toxic (unlike many of the poisons your doctors prescribe), even if it is only a placebo effect I have the right to choose what I feel is right for me. That choice does not belong to you so mind your own business, which is to prescribe allopathic medication and treatment plans.

Most doctors feel under constant pressure from drug companies that are owned by large national corporations, and I wonder if the pressure to ban complementary medicines comes from them?

I am not anti medical intervention, however get your heads out of the sand, the earth is in crisis and the waterways have antibiotics in them that are entering the food chain.
Leave complementary medicines alone and listen to what a high proportion of the population want, instead of a lot of old foggies.

Regards
Tamara York

From: Carole Young [redacted]
Sent: Thursday, 11 April 2019 4:53 PM
To: medboardconsultation
Subject: Medical Board Submission

To whom it may concern

“I believe that doctors should adhere to the current CODE OF GOOD MEDICAL PRACTISE where they are able to think FREELY and act in accordance with their patients wishes using BEST AVAILABLE evidence and their clinical judgement”.

Carole Young
[redacted]

From: [redacted]
Sent: Tuesday, 14 May 2019 11:35 AM
To: medboardconsultation
Subject: Integrative Medicine
Attachments: [redacted]

To whom this may concern,

I am emailing to express concern that you are looking to limit and control what Integrative Doctors can prescribe by monitoring and restricting their practice. I am someone who regularly sees an Integrative Doctor and have done since 2017. I have achieved multiple, fantastic improvements to my health to a degree that does not compare to that of regular GPs and even some specialists, to which I have seen many over the years. I feel that this is a gross limitation on my rights to seek the appropriate medical attention. To put these limitations in place is to not only deny my individual rights, but will also deny thousands of other patients their rights to appropriate treatment and also to those professionals who have worked very hard to gain their accreditations in their respected field.

I request Option One and if you would like to contact me, please feel free.

Regards,

Dean Young
[redacted]

From: [redacted]
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments'.
Date: Thursday, 2 May 2019 1:10:44 PM

To whom it may concern,

I am writing in response to provide feedback regarding recent concern that there maybe change of policy to regulation on integrated and complementary medicine.

I strongly support that there should not be any change to the current guideline as integrative medicine brings a holistic approach to looking after patients. As a doctor and also as a patient, we want doctors that will care for us as a whole, and integrative medicine bring in dietary, vitamins, environmental consideration and many other aspects of management of health that traditional medicine will often not consider. We all understand and know that there are limitations to traditional medicine, which can be complemented when integrative medicine is added to the management of the patients. Medicine and understanding of human body is always evolving and just because a lot of the studies re importance of integrative medicine is emerging, it does not mean that it is not effective and should be restricted. It is vital that practice of medicine should be focused on preventing disease and integrative medicine has a large focus on preventative medicine and encouraging patients to look after their health in a holistic manner.

In my practice as a GP, patients find it invaluable to have doctors that can give them wider options of treatments, and I have found in many occasions, integrative medicine offer management to patients that bring cure and health that traditional medicine alone is unable to offer.

If MBA imposes restrictions on integrative practitioners, it will largely limit the freedom for doctors to practice what they need to do and patient's care will be affected.

Thank you for your consideration. I know as a board, you have have in mind the best interest for patients and I believe integrative medicine brings just that to our patients.

Kind regards

Dr Tanya Yuen (GP)

From: [redacted]
Sent: Tuesday, 26 February 2019 5:40 PM
To: medboardconsultation
Subject: Tell us what you think about our draft guidelines on complementary and unconventional medicine and emerging treatments

Dear Sir/Madam

The problem with all complementary medicines which are not favoured by mainstream medical practitioners, is that the so-called medicines keep the patient from the mainstream treatment/medication. The cornerstone of the argument for those complimentary medicines by their advocates is that "they don't do harm". In fact, they do harm by keeping patients from the appropriate treatments.

Medical board can use a simple test to decide whether to give OK to any of those so-called medicines: Does the complementary medicine have the potential of keeping a patient from proper treatment? If yes, it should not be sold to anyone.

Kind regards
Dr Mehdi Zahedpur FRACGP

1. Do you agree with the proposed term ‘complementary and unconventional medicine and emerging treatments’?

   yes

2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – ‘any assessment, diagnostic technique or procedure, diagnosis, practice,[4] medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.’

   yes

3. Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide ‘complementary and unconventional medicine and emerging treatments’?
4. Are there other concerns with the practice of ‘complementary and unconventional medicine and emerging treatments’ by medical practitioners that the Board has not identified?
5. Are safeguards needed for patients who seek ‘complementary and unconventional medicine and emerging treatments’?
6. Is there other evidence and data available that could help inform the Board’s proposals?

Options

7. Is the current regulation (i.e. the Board’s *Good medical practice*) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?

   yes

8. Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?

   I don’t think the issues are identified have any ground. Conventional medicine does not offer patients any answer or effective treatment for most chronic conditions. Even when it does, the patient should be free to choose whichever treatment they feel is most suited to them. I don’t think restricting unconventional therapies even more would benefit the patients in any way. I am a cancer survivor who recovered from cancer without any conventional medicine.

9. The Board seeks feedback on the draft guidelines (option two) – are there elements of the draft guidelines that should be amended? Is there additional guidance that should be included?

   I don’t think they are needed at all.

10. Are there other options for addressing the concerns that the Board has not identified?

    The concerns identified are misplaced.

11. Which option do you think best addresses the issues identified in relation to medical practitioners who provide complementary and unconventional medicine and emerging treatments?
    1. • Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.
    2. • Option 2 - Strengthen current guidance for medical practitioners who provide complementary and unconventional medicine and emerging treatments through practice-specific guidelines that clearly articulate the Board's expectations of all medical practitioners and supplement the Board's *Good medical practice: A code of conduct for doctors in Australia*.
    3. • Other – please specify.

    Option 1. I think the current status quo is adequate.

From:	n zimmerman
To:	medboardconsultation
Subject:	Consultation on complementary and unconventional medicine and emerging treatments
Date:	Saturday, 22 June 2019 7:18:28 PM
Attachments:	Consultation on complementary and unconventional medicine and emerging treatments_Submission from Dr N Zimmerman.docx

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Please find submission attached.
Yours sincerely
Dr. Norman Zimmerman
Consultant Psychiatrist
[redacted]

Medical Board of Australia
Consultation on complementary and unconventional medicine and emerging treatments

There may be possibly unintended consequences of the proposed guidelines for medical specialists working with emerging treatments. In particular guideline 6.3 (*Ensuring that the provision of any complementary and unconventional medicine and emerging treatments comply with any relevant Therapeutic Goods Administration requirements)* should be amended. It could conflict with COAG Principle C *(Whether the proposal results in an unnecessary restriction of consumer choice).*

Concern 1:

I am a psychiatrist with an interest in an emerging form of brain stimulation called transcranial direct current stimulation (tDCS). This is being used to treat depression (1), treatment resistant schizophrenia (2) and potentially other psychiatric disorders. It uses two 9V batteries to apply a very weak current (around 2mA) to the head. While it is a weak treatment compared to electroconvulsive therapy (ECT) the advantage is that there is no anaesthetic and no cognitive side effects. The advantage over transcranial magnetic stimulation (TMS) is that tDCS is cheap and can be done at home. Recently Professor Colleen Loo, a world expert in neurostimulation from UNSW, published a trial using home based tDCS for depression highlighting the safety of this treatment (1). I have done the training with Professor Loo and am starting to offer tDCS to patients where conventional treatment doesn't work or is not tolerated. tDCS is clearly an emerging treatment and there is a risk that the proposed guidelines could stifle development in this area.

Once concern is about the choice of the actual tDCS device itself. After careful research I have been recommending a device from Hong Kong developed specifically for tDCS (3). It is not TGA approved and has no other regulatory approval. However it has been used in published studies in Australia and overseas (4,5,6,7). The cost of this device is $389 US dollars. There are two TGA approved devices but their costs are $5000 USD and $5500 USD. The current proposal 6.3 (*Ensuring that the provision of any complementary and unconventional medicine and emerging treatments comply with any relevant Therapeutic Goods Administration requirements)* would force patients to buy a more expensive device. The cost difference of over $7,000 AUD would prohibit most patients from considering this treatment. I think this is against the COAG Principle C *(Whether the proposal results in an unnecessary restriction of consumer choice).*

Concern 2:

Another concern with 6.3 is off-label prescription of medicines.

One established treatment which is not TGA approved is lamotrigine. This is now an accepted treatment for bipolar disorder. But being an old drug with multiple generics it has never been TGA approved for this indication.

From time to time other drugs will be prescribed off-label where the indication is less accepted but still based on published research. One example is minocycline for treatment-resistant schizophrenia. This would be considered an unconventional and emerging treatment.

Based on these concerns I suggest the Board amends 6.3 to something like:

Where any complementary and unconventional medicine and emerging treatment does not comply with Therapeutic Goods Administration requirements this is disclosed to and discussed fully with patients. The discussion should inform patients of similar medicines and treatments that are TGA approved. The reasons and evidence for suggesting a non TGA approved medicine or treatment should be fully discussed.

References:

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2. Kantrowitz JT, Sehatpour P, Avissar M, Horga G, Gwak A, Hoptman MJ, Beggel O, Girgis RR, Vail B, Silipo G, Carlson M, Javitt DC. Significant improvement in treatment resistant auditory verbal hallucinations after 5 days of double-blind, randomized, sham controlled, fronto-temporal, transcranial direct current stimulation (tDCS): A replication/extension study. Brain Stimul. 2019 Mar 5. pii: S1935-861X(19)30082-8.

3. tDCS Stimulator (1ch) MANUAL [Internet]. Hong Kong: TCT Research Limited; 2012. Available from: https://www.trans-cranial.com/docs/tdcs_1ch_man_v1_3_a_pdf.pdf

4. Doeltgen SH, Young J, Bradnam LV. Anodal Direct Current Stimulation of the Cerebellum Reduces Cerebellar Brain Inhibition but Does Not Influence Afferent Input from the Hand or Face in Healthy Adults. Cerebellum. 2016 Aug;15(4):466-74.

5. Narayanaswamy JC, Jose D, Chhabra H, Agarwal SM, Shrinivasa B, Hegde A, Bose A, Kalmady SV, Venkatasubramanian G, Reddy YC. Successful Application of Add-on Transcranial Direct Current Stimulation (tDCS) for Treatment of SSRI Resistant OCD. Brain Stimul. 2015 May-Jun;8(3):655-7.

6. Shenoy S, Bose A, Chhabra H, Dinakaran D, Agarwal SM, Shivakumar V, Narayanaswamy JC, Sivakumar PT, Venkatasubramanian G. Transcranial direct current stimulation (tDCS) for auditory verbal hallucinations in schizophrenia during pregnancy: a case report. Brain Stimul. 2015 Jan-Feb;8(1):163-4.

7. Narayanaswamy JC, Jose D, Chabra H, Agarwal SM, Shrinivasa B, Hegde A, Subramaniam A, Bose A, Kalmady SV, Venkatasubramanian G, Reddy YCJ. Transcranial Direct Current Stimulation of Pre-Supplementary Motor Area for SSRI resistant OCD. Brain Stimul. 2015 Mar–Apr;8(2):372.

From: Aneta Zydzik [redacted]
Sent: Friday, 28 June 2019 6:28 PM
To: medboardconsultation
Subject: Consultation on complementary and unconventional medicine and emerging treatments

Dear Sir/Madame,

it came to my attention that the future of integrative doctors in Australia is under threat. As Australian Citizen and European Union Citizen I strongly oppose such and would hope that MBA, following countries like Switzerland, would actually promote and encourage integrative medical advise as such has been proven efficient.

I myself have a long and successful history with IM, which helped me combat health issue that traditional GPs and specialists couldn't for years! This is also a pathway we have chosen for our kids who are strong and healthy and I appreciate doctors who can look into i.e.
diet, nutrition and other ways to prevent illnesses and treat them when they happen. This has been proven very efficient for my family while most of my friend's has been just advised on taking Panadol or prescribed other drugs.
It would be indeed backward solution for Australian citizens if we didn't have access to IM in our country.

I hope, you will stay true to the Hippocratic Oath and despite the influences you may be under, will keep patients's wellness a priority.
It is in fact health, wellbeing and productivity of your citizens and tax payers that is at stake.

Many thanks.

Best regards,
Aneta